Environmental Fate and Effects Division's Risk Assessment for the Section 3 Use of Novaluron on Cotton, Pome Fruit and Potatoes

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APPENDIX LIST

I. Environmental Risk Conclusions

Environmental Fate and Risk Summary

Pesticide Chemistry and Environmental Fate

The risk assessment is based on supplemental and acceptable environmental fate and ecological effects data. Novaluron is a chiral compound containing a racemic mixture of two enantiomers (R,S). The available environmental fate and ecological effects data on novaluron represents only the racemic mixture. Additional data on individual enantiomers may be required if the registrant chooses to develop isomeric enriched products of novaluron.

Novaluron is immobile and non-persistent in soil laboratory studies. However, it appears to be more persistent in some field studies under actual use conditions. Novaluron persistence in field soils may be partially explained by temperature effects on metabolism; greater persistence is found in cooler climates. Metabolites of novularon with human-health toxicological concern are chlorophenyl urea (1-[3-chloro-4-(1,1,2-trifluoro-2-trifluroromethoxyethyoxy) phenyl] urea) (termed chlorophenyl urea (275-352I)) in this risk assessment and chloroaniline (3-chloro-4-(1,1,2-trifluro-trifluroromethoxyethoxy)aniline). Because novaluron can be aerially and ground spray applied as well as exhibits high soil:water partitioning coefficients, novaluron movement from the application site is expected to depend on runoff of entrained sediments and spray drift.

Aquatic Organism Risks of Concern

The mechanism of action of action of novaluron suggests that the compound would pose a toxic hazard to invertebrates, especially during molting life stages. Available laboratory toxicology data do indeed indicate that novaluron is highly toxic to freshwater and marine invertebrates. A comparison of these data with estimated levels of aquatic exposure leads EFED to conclude that there is a concern for the potential acute risks to freshwater and marine invertebrates for all crops considered in the risk assessment (cotton, pome fruits, and potatoes). The same conclusions have been reached for chronic risks to freshwater and estuarine/marine invertebrates. Analysis of spray drift loadings of novaluron to surface water also exceeds levels of concern for invertebrate risks. Furthermore, a comparison of formulated product toxicity data and formulated product concentrations in surface waters receiving spray drift indicates that short term exposures to the formulated product may also be a risk concern for aquatic invertebrates. The concerns for adverse impacts on aquatic invertebrates are supported by available aquatic invertebrate microcosm studies, performed at environmentally relevant novaluron concentrations, that show reductions in aquatic invertebrate populations. Some of the invertebrate taxa impacted in the microcosm study never recovered for weeks following initial pesticide exposure, raising concern for possible long-term alterations to aquatic communities.

Because of the potential for novaluron degradation and dissipation in aquatic systems, the risk assessment considered a number of averaging times for water concentration modeling purposes. The resulting averaging-time specific and compared the results of the exposure model output with long-term lethality testing results for aquatic invertebrates. This approach found that risk concerns for lethal effects in aquatic invertebrates were upheld regardless of the averaging time considered. Furthermore, available aquatic invertebrate microcosm studies, performed at environmentally relevant novaluron concentrations, show reductions in aquatic invertebrate populations, some of the taxa affected never recovered for weeks following initial pesticide exposure.

Aquatic invertebrates play a critical role as an important food source for aquatic vertebrates (e.g., fish) in aquatic ecosystems. The observations of significant community disruptions in microcosm studies and the high magnitude of risk quotient results suggest that impacts to aquatic invertebrate communities may be severe and for some elements of the community prolonged. These effects may indirectly impact fish growth, reproduction, and abundance in areas where novaluron is used. The proposed target crops (pome fruit, cotton, and potatoes) suggest that novaluron has the potential for widespread use and therefore a variety of aquatic communities may be exposed and adversely impacted.

Novaluron physical chemical properties suggest that the compound has a tendency to adsorb to soil and sediment. The risk assessment considered the results of benthic invertebrate microcosm testing to evaluate the potential for adverse effects on such invertebrates. The microcosm data showed that environmentally relevant novaluron concentrations, even below the level of detection, can produce severe and long-lasting impairment of populations of benthic invertebrates. Laboratory testing of novaluron effects on sediment organisms may be very useful for quantifying the potential risk of the compound to benthic invertebrates, provided the exposure protocols are of sufficient duration to encompass multiple life stages of the test organism. Prolonged exposure durations would be necessary because novaluron exerts toxic effects at critical life stages in the developing invertebrate and so lengthy exposure periods allow for sufficient overlap of chemical exposure with those life stages. Laboratory toxicity tests would also be instrumental in establishing detection limit targets for the development of a needed analytical method capable of detecting novaluron at biologically relevant levels.

Risks for Piscivorus Wildlife

A preliminary analysis of the potential risks of novaluron bioconcentrated in fish to piscivorus wildlife was conducted as part of the risk characterization. This analysis suggests that, in all cases that EECs averaged over shorter periods may potentially result in whole fish novaluron concentrations that would exceed chronic toxicity thresholds for birds but not mammals. Longer averaging times for EECs, result in lower estimated water concentrations, and, in the case of cotton and potato uses, may result in fish concentrations of novaluron below chronic toxicity thresholds for birds and mammals. Averaging times for novaluron in surface waters between 21-days and 60 days may be the most appropriate for estimating bioconcentration potential because peak whole fish concentrations were not reached until 35 days of exposure in the lab for the bluegill sunfish test species. The EECs and corresponding whole fish novaluron estimates for these averaging times fall close to, but on either side of, the chronic toxicity threshold in birds. Bioconcentration factors for fish species other than the bluegill sunfish are an order of magnitude below the bluegill sunfish BCF, and predicted fish concentration would be well below the avian chronic toxicity threshold if these BCF values were used instead of the bluegill. On the basis of this preliminary analysis, there appears to be a potential concern for risks to piscivorus birds, but the extent to which this route is toxicological concern is uncertain across potentially exposed aquatic systems and for differing patterns of novaluron residues in surface waters. Differences in species BCF, and patterns of water concentration decline are important factors in the analysis. Monitoring of fish concentrations of novaluron under field use conditions would provide data important for further evaluation of the significance of this exposure route.

Terrestrial Vertebrate Risks of Concern

Acute risks to birds and mammals did not exceed levels of concern. However, chronic risk quotients for birds ranged from 19.5 on short grass to 2.9 to 0.3 on fruit, pods, seeds, and large insects. To further evaluate the chronic avian LOC exceedance for birds, EFED evaluated the impact of various foliar dissipation half-lives of (1, 5 and 35 days (default)) on novaluron residue concentrations and their impact on risk conclusions Chronic avian LOCs are exceeded for all crops at all avian food sites (except the fruits, pods, seeds, and large insect sites) regardless of the assumed foliar half-life. However, the chronic avian risk for tall grass forage sites was reduced below the level of concern using a 1 day foliar half-life. The results of this analysis suggest that additional data on residue dissipation in avian food sources may not be significant to alter screening level assessment conclusions of potential avian chronic risk, but such data may be valuable should more species-specific assessments be conducted that would require consideration of specific dietary behaviors.

Chronic avian risk was also evaluated for single applications of novaluron and assumptions of maximum and mean residues. For maximum residue assumptions, risk quotients exceeding the chronic LOCs for all food categories except the fruit, pod, seed, and large insect category for maximum residues for all crops. Risk quotients ranged from 0.12 to 7.4. The chronic LOCs were exceeded for the short grass, tall grass, and broadleaf/forage plants and small insect categories only for pome fruit for mean residue assumptions. These risk quotients ranged from 1.2 to 2.3. The confidence in the chronic avian risk conclusion is buttressed by these findings.

Proposed banded applications of novaluron to cotton only exceeded levels of concern for endangered species for 15 gram birds when the application rates were not adjusted for band width. If the rates were adjusted for band width, the acute risk resulting from banded applications could be effectively mitigated

Terrestrial Invertebrate Risks of Concern

Available data for adult honeybees classifies novaluron (Rimon technical) and the formulated product as practically non-toxic to adult honeybees. The LD_{50} for the technical novaluron was > 100 μg/bee while that of the Rimon 10EC formulated product was LD_{50} >200 μg/bee. EFED currently does not quantify risks for terrestrial non-target insects. When an LD_{50} is < 11 μg/bee an appropriate label statement is required to protect foraging honeybees. At first glance, the available adult honeybee testing would suggest that there would be little concern for non-target insects. Given that the novaluron mechanism of action (chitin biosynthesis inhibition) is targeted to developing insects, it is evident that reliance on adult insect toxicity testing is inadequate for evaluating novaluron effects in non-target insect. Additional non-target insect studies are available that demonstrate adverse effects on honey bee brood development at all growth stages and significant effects on wasp and predatory mite populations. These effects demonstrate that beneficial non-target insects may be at risk immediately after spray applications. The available non-target insect data also demonstrate that non-target insects may recover over time, either as novaluron dissipates from the treatment area, or when insects are moved from the treatment area to untreated locations. In total, these findings suggest that the use of novaluron may adversely impact integrated pest management programs as well as pose challenges for honeybee and solitary bee pollinator operations.

Drinking Water Summary

Tier II PRZM/EXAMS modeling was performed for novaluron to estimate drinking water concentrations for the human health dietary risk assessment. Because of limited environmental fate data, a Tier I drinking water assessment was performed for novaluron degradates, 1-[3-Chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]urea (275-352I) and 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline (275-309I).

The most conservative estimates were obtained for airblast applications of novaluron to PA apples at the maximum annual application rate of 0.96 lb a.i./acre, applied three times at 0.32 lbs a.i./acre with an interval between applications of ten days. The predicted 1 in 10 year annual peak concentrations of novaluron in surface source water was 11.4 μg/L. It is important to note the predicted peak exceeds the solubility of the compound (3 μg/L), which is likely to be an upper bound concentration in drinking water. The estimated 1 in 10 year annual mean concentration of novaluron in drinking water is 1.8 μg/L. The 30-year annual mean concentration is 1.2 μg/L. Both peak and annual average concentrations for all other scenarios were lower.

An estimated peak drinking water concentration in surface water sources is 4.6 μg/L for chlorophenyl urea and 11.4 μg/L for chloroaniline based on novaluron's maximum application rate of 0.32 lbs a.i./acre applied 3 times a season (0.96 lbs ai/year; apples). The estimated annual average concentration is 0.86 μg/L for chlorophenyl urea (275-352I) and 2.6 μg/L for chloroaniline.

II. Introduction

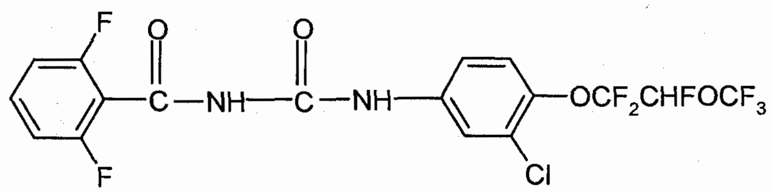
Novaluron is an insect growth regulating insecticide in the benzoylphenyl urea family which acts on the pest larval stage by inhibiting chitin biosynthesis and blocking the cuticle formation in target pests. It is currently registered for ornamental use in greenhouse and shadehouses. The current registration application is for a Section 3 use on pome fruit, cotton, and potatoes. Specific information about this proposed registration is presented below.

Physical and Chemical Properties of the Pesticide

Common name:	Novaluron
PC Code:	124002
IUPAC name:	1-[3-chloro-4-(1,1,2-trifluoro-methoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea
CAS Name:	`[[[3-Chloro-4-[1,1,2-trifluoro-2-

	(trifluoromethoxy)ethoxy]phenyl]-amino]carbonyl]-2,6-difluorobenzamide	
CAS Number:	116714-46-6	
Molecular formula:	$C_{17}H_9ClF_8N_2O_4$	
Molecular weight g/mole):	492.7	
Water Solubility:	3 ug/L @ 25 ^{0}C	(MRID 45638203)
Vapor pressure:	1.2 x 10^{-7} mm Hg	
Henry's Law Constant:	2.0 Pa m^3/mol^{-1}	
Log K_{ow}:	4.3	(MRID 45638405)

Chemical structure of Novaluron:



Pesticide Mode of Action

Novaluron is a benzoylphenyl urea insect growth regulating insecticide. Its larvacidal action results from the inhibition of chitin biosynthesis and interference in the cuticle formation in target pests. To be fully effective novaluron must be ingested by insect larvae. Rimon™ has no effect on adult insects that have completed all successive molts, and hence implies that the product could be used concurrently with insects released for biocontrol of plant pests. However, the label points out that the compatibility with such integrated pest management approaches has not been established.

Proposed Uses and Use Characterization

For food use, the registrant proposed two novaluron formulations: 7.5% water dispersible granule (RimOn 7.5WDG) insect growth regulator for control of insect pests on apples and pears and 10% emulsifiable concentrate (RimOn 10EC) insect growth regulator for use on cotton and potatoes. Application by chemigation is prohibited for all proposed uses.

The insecticide is applied to the foliage of apples and pears by conventional ground sprayer or airblast sprayer at increased pressure and high volume. According to the proposed label no more than 0.96 lbs a.i. (RimOn 7.5WDG) may be applied per acre per season, with the maximum rate per application 0.32 lbs a.i., the minimum intervals of 10 to 14 days between applications, and up to 3 applications per season are allowed. No application should be made within 14 days of fruit harvest.

RimOn 10EC is applied to cotton via conventional ground or aerial sprayer, or via band application when cotton plants are small. The maximum proposed application rate is 0.27 lbs a.i. (RimOn 10EC) per acre per season, with the maximum rate per application of 0.09 lbs a.i., a minimum interval of 7 to 14 days between applications, and up to 3 applications per season. No instructions were on the label concerning the band width and its corresponding application rate within the band or the width of the untreated areas between the rows. Therefore, an assumption of 6 inch bands with 30 inch row spacings was assumed for the purposes of this risk assessment. No application should be made within 30 days of cotton harvest.

RimOn 10EC is applied to potatoes by conventional ground spray or aerial equipment. The maximum proposed application rate is 0.23 lbs a.i./A per season, with the maximum rate for a single application rate of 0.078 lbs a.i./A. Up to three applications per season could be applied at intervals of 10 to 14 days between applications.

Risk Assessment Approach

Assessment Chemicals of Concern

The risk assessment considers aquatic and terrestrial risks for the active ingredient novaluron. In addition, the assessment considers risks posed to aquatic organisms from the chlorophenyl urea degradate (275-352I), and the formulated product Rimon 10EC.

Assessment Endpoints

The typical assessment endpoints for screening-level pesticide ecological risks is reduced survival and reproductive impairment for both aquatic and terrestrial animal species. These effects extend to a consideration of direct acute and direct chronic exposures. While these endpoints are measured at the individual level, they do provide insight about risks at higher levels of biological organization (e.g., populations).

Measures of Effects

The screening level risk assessment process relies on a suite of toxicity studies performed on a limited number of organisms in the following broad groupings:

- Birds (mallard duck and bobwhite quail) (see Toxicity to Birds section)
  - Acute and chronic data are complete for this risk assessment
- Mammals (laboratory rat)(see Toxicity to Mammals section)
  - Acute and chronic data are complete for this risk assessment
- Freshwater fish (bluegill sunfish, rainbow trout, and fathead minnow)(see Toxicity to Fish section)
  - Acute data set is available for novaluron, however the endpoints available are uncertain

- Acute data are available for formulated product, these data are incorporated into risk assessment through analysis of drift exposure risks
- Acute data are available for chlorophenyl urea degradate 275-352I
- Chronic freshwater fish data are available for novaluron

- Freshwater invertebrates (*Daphnia magna*)(see Toxicity to Aquatic Invertebrates section)
  - Acute data are not available for novaluron, extrapolations are made from other data
  - Acute data are available for formulated product but measured active ingredient concentrations are uncertain
  - Chronic data set is available
  - Acute data are available for chlorophenyl urea degradate 275-352I
- Estuarine/marine fish (sheepshead minnow)(see Toxicity to Fish section)
  - Acute data are available for novaluron, however the endpoints available are uncertain
  - No chronic data were available
- Estuarine/marine invertebrates (*Crassostrea virginica* and *Mysidopsis bahia*)(see Toxicity to Aquatic Invertebrates section)
  - Acute data are available for novaluron and formulated product
  - Chronic data are available for novaluron
- Terrestrial plants (corn, soybean, carrot (radish or sugar beet), oats (wheat or ryegrass), tomato, onion, cabbage (cauliflower or brussels sprout), lettuce, cucumber)
  - No data were available, quantitative assessments of risks thus not performed
- Algae and aquatic plants
  - Data were available for green algae and aquatic vascular macrophytes for novaluron, formulated product, and chlorophenyl urea degradate 275-352I

Within each of these very broad taxonomic groups, an acute and chronic endpoint is selected from the available test data, as the data sets allow. The selection is made from the most sensitive species tested within that organism group.

Additional effects data were available for other taxa and for aquatic community effects measures. These have been incorporated into the risk characterization as other lines of evidence. These data include:

- Microcosm studies of primary production and invertebrate responses in a small-scale aquatic community
- Acute laboratory toxicity study of technical and formulated product with oligochaete worms
- Toxicity data on beneficial insects
  - laboratory tests for honeybee contact toxicity
  - honey bee brood development studies under field conditions
  - non-target arthropod study in citrus groves

A complete discussion of all toxicity data available for this risk assessment and the resulting measurement endpoints selected for each taxonomic group are included in the Sections VI and VII of this document.

Measures of Exposure

Exposures estimated in the screening level risk assessment for non-target organisms are not specific to a given species. Rather, general taxonomic exposure assumptions are made that provide separate exposure measures for aquatic and terrestrial plants and animals. The approaches for each are discussed separately below.

Aquatic Organisms

The principal exposure concern for novaluron is the exposure of aquatic organisms to the active ingredient. However, additional data are available for the degradate chlorophenyl urea (275-352 I) in fish and aquatic invertebrates, suggesting that exposure modeling for these degradates is warranted. In addition, acute toxicity data for Rimon 10 EC, the formulated product is available and suggest that one or more constituents of the formulated product may exert toxic effects on fish. Therefore, formulated product exposure modeling was also included in the risk assessment. The following sections describe the general analysis approach used for active ingredient, degradate and formulated product exposure assessment.

Active Ingredient and Degradate Aquatic Organism Exposure Approach

This risk assessment considers novaluron exposure in aquatic organisms (animals and plants) via the fraction of pesticide dissolved in the water column. Novaluron is assumed to be introduced to surface waters via runoff and spray drift. Because novaluron is a new pesticide, no monitoring data are available that would provide information on novaluron levels in surface water bodies receiving runoff or spray drift from agricultural fields treated with the pesticide. Consequently, aquatic organism exposure is estimated through the use of runoff and drift models, using a standardized surface water body. Aquatic organism exposures are based on a set of standardized water body assumptions (water body size, watershed size, proximity to field, etc.) that result in high-end estimates of exposure. For this risk assessment the PRZM/EXAMS model was used for making these exposure estimates. Crop scenarios were selected to provide high-end concentrations in drinking water and aquatic environments for each crop and represent the geographic locations where the specific crops are grown in large quantities. Runoff scenarios for novaluron were Pennsylvania, North Carolina and Oregon apples (airblast application), Mississippi cotton (ground and aerial application), and potato in Maine (ground and aerial application). In addition to the drift and runoff combination for the active ingredient surface water modeling, the risk characterization section of this document also describes the exposures limited to spray drift alone. This was accomplished through the simple dilution of an assumed deposition of 5% of the application rate to a 20 million liters

Degradate exposure analysis is similar to that performed for the active ingredient, except the GENEEC model is used because of the limited fate data set for the degradate. The initial production of degradate in the field is determined though analysis of available environmental fate studies that track the formation of the degradate from various degradation pathways.

For acute aquatic risk assessment purposes, no averaging time for exposure was assumed for this risk assessment. An instantaneous peak concentration, with a 1 in 10 year return frequency, is used. The use of the instantaneous peak assumes that instantaneous exposure is of sufficient duration to elicit acute effects on par with those observed over more protracted exposure periods tested in the laboratory, typically 48 to 96 hours. For assessment of chronic aquatic invertebrate risks with novaluron, the peak water concentration was again used. This is a departure from the normal assessment where peak 21-day average, 1 in 10 year return frequency values is the measurement endpoint for aquatic invertebrate chronic risk assessment. The decision to use a peak concentration exposure measure was predicated on data available for another chitin inhibiting insect growth regulators, of similar chemical structure and mode of action (diflubenzuron), that suggest effects observed in most chronic invertebrate tests with such pesticides are actually the product of short-term exposures of developing organisms at critical periods of the development cycle (i.e., molting).

Formulated Product Aquatic Organism Exposure Approach

Rimon 10 EC exposures for acute aquatic risk assessment were assessed for the aerial drift pathway to surface water. Drifted formulated product mass is assumed to be instantaneously mixed with the surface water in a standardized water body with a volume of 20 million liters.

Terrestrial Animals

The focus of a terrestrial wildlife exposure assessment is on birds and mammals with the exposure route emphasis on uptake through the diet. For exposure to terrestrial organisms, such as birds and small mammals, OPP mostly looks at the residues of pesticides on food items and assumes that organisms are exposed to a single pesticide residue in a given exposure scenario. For novaluron spray applications, estimation of pesticide concentrations in wildlife food items focuses on quantifying possible dietary ingestion of residues on vegetative matter and insects. The residue estimates are based on a nomogram that relates food item residues to a pesticide's application rate. Residues may be compared directly with dietary toxicity data or converted to an oral dose, as is the case for small mammals. The screening-level risk assessment for novaluron uses an upper bound predicted residue as the measure of exposure. For mammals, the residue concentration is converted to daily oral dose based on fractions of body weight consumed daily as estimated through mammalian allometric relationships.

An additional analysis was performed for banded applications of novaluron to cotton. The exposure term used for this assessment involved the mass of pesticide per unit area (mg a.i./ft^2), an index of potential bioavailability that considers multiple routes of exposure, though none with a specific quantitative measure of relative contribution. Because the label of novaluron does not clearly present the application rate as the amount per acre of field or per acre of treated bands, the assessment considered a scenario where the application rate relates to the whole field and where the application rate refers to the bands alone. This mass per unit areas is then compared to toxicity endpoints expressed in terms of mass/animal equivalent to an LD50.

Risk Characterization Approach

For this assessment of novaluron risks, the risk quotient (RQ) method is used to compare exposure and measured toxicity. Estimated environmental concentrations (EECs) are divided by acute and chronic toxicity values. The RQs are compared to the Agency's levels of concern (LOCs). These LOCs are the Agency's interpretative policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide uses as directed on the label has the potential to cause adverse effects on non-target organisms. Appendix D of this document summarizes the LOCs employed in this risk assessment.

III. Integrated Environmental Risk Characterization

Risks to Aquatic Organisms

Novaluron is immobile and non-persistent to moderately persistent in soil and aquatic environments. Because novaluron has a high sorption affinity to soil/sediment, it is expected sorb strongly to soil and sediment and so may constitute a route of exposure (sediment to pore water to an organism) for benthic organisms. It is expected to move from the target application site on entrained sediments in runoff and spray drift.

The results of the risk assessment suggest that acute and chronic risk to freshwater and marine invertebrates are the principal concern for direct toxic effects in aquatic ecosystems. All the calculated risk quotient values (RQs) for these invertebrates were above the acute risk and chronic risk levels of concern established by the Agency for screening-level risk assessment. The chronic invertebrate risk quotients range from 3 on potatoes to 194 on pome fruit. Acute invertebrate quotients range from 0.6 to 42. In addition, the potential for novaluron to adsorb to sediments, combined with microcosm observations of benthic invertebrate community effects at environmentally relevant novaluron loadings, suggest that concern for risks to invertebrates extends to the benthic community as well. The risks associated with all the aquatic organism groups are outlined in more detail below.

Aquatic Invertebrates

Risk quotients (Appendix E) for acute risks to freshwater invertebrates for parent novaluron range from 6 to 34, all crop scenarios modeled were in excess of acute risk concern levels. These RQs were based on an extrapolated toxicity value because the available acute aquatic invertebrate toxicity study using parent novaluron was found to be invalid. The freshwater invertebrate toxicity of novaluron was extrapolated from an available chronic endpoint for daphnids, modified by an established acute to chronic ratio for marine invertebrate toxicity endpoints. Attributing an acute to chronic ratio from estuarine/marine invertebrate test data to freshwater invertebrates is uncertain. However, the extrapolated freshwater invertebrate toxicity endpoint would have to be assumed conservative by more than an order of magnitude for resulting risk quotients to be below the acute toxic risk level of concern. It is therefore concluded that predictions for acute effects in freshwater invertebrates are not likely to be grossly overestimated by the toxicity extrapolation approach employed in this risk assessment.

Estuarine/marine invertebrate acute RQs (Appendix E) for parent novaluron (7 to 39) indicate that the acute risk level of concern is exceeded at all proposed use sites. Of course, a potential source of uncertainty associated with the estuarine/marine risk assessment is the degree to which existing water models adequately represent estuarine/marine environments. It is conceivable that loadings to estuarine/marine environments may differ from freshwater systems. However, loadings to near-shore, shallow water systems, important to the productivity of estuarine systems would have to be more than 10 times lower than those modeled for there not to be a concern.

Previous review (MRID 44460701 and 44460702) of another chitin inhibitor, diflubenzuron, established that there is a "narrow window of sensitivity in the molt cycle that is highly susceptible to inhibition of chitin formation" and that acute LC50s for specific life or molt stages are similar to chronic NOAEC values. Analyses of diflubenzuron risks to aquatic invertebrates considered the effects of exposure averaging time on the conclusions of the risk assessment, taking into account the likely acute sensitivity of invertebrates at critical stages of the life cycle. While not from a standard guideline testing procedure, the registrant data submissions included 28-day LC50s for freshwater and marine invertebrates: 0.0579 and 0.1 ug/L, respectively. These LC50 values are remarkably close to the chronic toxicity thresholds measured for freshwater and estuarine/marine organisms, suggesting that the critical life stage observation for diflubenzuron may also occur for novaluron. These 28-day LC50 endpoints likely are of sufficient duration to cover multiple stages of the test organism life cycle and can be used to investigate the potential for other exposure averaging time assumptions (beyond the single day instantaneous peak), on the risk assessment conclusions for aquatic invertebrate mortality risks. Appendix E aquatic organism RQ tables present peak, 21-day and 60-day surface water concentration estimates for each use site modeled. Using the peak concentrations of 0.94 ug/L for potatoes, a use site with the lowest use rate, the water concentrations would far exceed the LC50 values by factors of 16 for freshwater and 9.4 for estuarine/marine invertebrates. When considering the peak water concentrations for the pome fruit scenario, exposures would exceed these LC50s by factors of 87 to 50 for freshwater and estuarine/marine invertebrates, respectively. To further investigate the potential effects of exposure concentration averaging time on the risk conclusions, these 28-day toxicity values can also be compared with other time-weighted average concentrations from the modeling output. Such a comparison with the potato scenario 21-day average concentrations shows that exposures exceed the freshwater and estuarine/marine 28-day LC50 values by factors 11 to 7, respectively. Similar analysis with the higher use rate scenarios for cotton and pome fruits would yield exposures even higher than the demonstrated toxicity endpoints. Indeed, even a comparison of the estimated 60-day average novaluron concentrations in water show exposure exceeding the 28-day LC50s . This analysis further supports the risk assessment conclusions that freshwater and estuarine/marine invertebrates are at potential acute risk.

Valid chronic data were submitted for freshwater invertebrates as well as marine/estuarine invertebrates for parent novaluron. The chronic risk quotients for freshwater and marine invertebrates that are based on this toxicity data and modeled surface water concentrations range from 31 to 194. All use scenarios modeled are included in this range. Even though the mechanism of novaluron would suggest that chronic endpoints reflect acute responses at critical developmental periods in the invertebrate life cycle, the effect of exposure model averaging time was considered in the manner described for the long-term lethality methods described above. Employing longer averaging times for RQ calculation did not result in RQ values below concern levels for freshwater invertebrates, and for estuarine/marine invertebrates averaging time had no effect on the risk assessment conclusions until a two-month averaging time was considered. Owing to the high magnitude of the RQ values, it appears that steps to reduce exposure below chronic concern levels would require substantial reductions in loading rates to surface waters.

The risk assessment's RQ results for acute and chronic risk quotients suggest a concern for aquatic invertebrates. An additional line of information is also available to further characterize these risk concerns. Available microcosm data indicate that significant impacts to aquatic zooplankton and benthic macroinvertebrates can occur at nominal initial water concentrations of 0.05 to 5 ug/L. This range of concentrations encompasses all peak, 21-day and most 60-day (except the potato scenario involving ground application) 1 in 10 year return frequency estimates of novaluron in surface waters. Effects in this microcosm study include but are not limited to:

- Total measured zooplankton populations exhibited negative responses to novaluron, as compared to controls for all dose levels, with statistically significant population reductions ($p<0.01$) at the 0.15 through 5 ug/L dose levels (NOAEC.0.05 ug/L);
- Statistically significant ($P<0.01$ or $P<0.05$) reductions in population indices (NOAEC< 0.05 ug/L) for the following zooplankton taxa: Cyclopoidae (recovery after 84 days at this dose level), Chaoboridae (recovery by day 70), and Chirocephalidae;
- Statistically significant ($P<0.01$ or $P<0.05$) reductions in population indices (NOAEC 0.15 ug/L) for the following zooplankton taxa: Chydoridae, Lecanidae, and Diaptomidae;
- Benthic invertebrate community response (taxonomic response weighting) show statistically significant ($p<0.05$) community level effects at the 0.15 ug/L dose level, with a community level response NOAEC of 0.05 ug/L; and
- Complete eradication of all Gammaridae amphipod crustacean populations, at all novaluron concentrations tested NOAEC< 0.05 ug/L.

The aquatic habitats potentially affected by the proposed uses of novaluron on pome fruit, cotton, and potatoes may be extensive. Runoff and drift from spray applications to pome fruit could affect freshwater or marine invertebrate structure in nearby streams, marshes, ponds, wetlands, tidal pools, and other water bodies. Aquatic invertebrates that may be adversely affected by exposures to novaluron may play an important role as primary food sources for fish and other aquatic fauna. Though the available toxicity and exposure information preclude a quantitative assessment of the overall impacts, the demonstrated toxicity of novaluron to a variety of crustacean species and the observed impacts to invertebrate communities in microcosm studies at environmentally relevant novaluron concentrations suggests the potential for commercial crustacean fisheries (e.g., crabs, shrimp, etc.) impacts in the Gulf Coast region if cotton production use of novaluron resulted in the drift or runoff to important fishery habitats. Use in the cotton growing areas of California could potentially impact the ecological aquatic niches of healthy streams, ponds, wetlands, or other aquatic habitats that support healthy fisheries.

Aquatic invertebrate communities play a critical role as an important food source for aquatic vertebrates. Prolonged exposure from novaluron and its associated disruption of aquatic communities may have the potential to impact the fish growth, reproduction, and abundance. However, the level of analysis in this risk assessment cannot quantify the extent to which invertebrate community effects would impact aquatic vertebrates through food source impairment.

Sediment-Dwelling Organisms

Because novaluron is strongly sorbed to sediments and soils (K_{oc} = 6,680 - 11,813) it may be expected to partition to benthic substrates. No single-species toxicity data are available to quantitatively assess risks to individual benthic invertebrate species. However, data available for microcosms effects experiments (MRID 458858-01) suggest that populations of benthic invertebrates can be significantly reduced (up to total eradication in the case of Gammaridea) in aquatic systems where sediment concentrations of novaluron are below levels of detection (detection limit 5 ng/g). Observed impacts to some members of the benthic community were not followed by population recovery, suggesting either low potential for recruitment of new individuals or residual activity of novaluron when partitioned to sediments. Sediment toxicity data, which demonstrate the measured toxicity of novaluron in the sediment and interstitial water, would enable a more quantitative analysis of novaluron risks to sediment dwelling organisms, provided that protocols allow for exposure durations sufficiently lengthy to encompass multiple life stages of the tested organisms.

Fish

While acute RQs (Appendix E) can be tentatively calculated for fish, the interpretive value of these quotients has some limitations. The principal limitations to the interpreting these RQs are the quality of the acute toxicity data available and the peak surface water model estimates of concentration that, in certain use scenarios considered, exceed measured solubility limits in pure water. However, consideration of the actual observations of effects within each acute toxicity study (or lack of observed effects) and modeled surface water concentrations as compared to measured water solubility suggest that acute risk from the use of novaluron, its formulated product (Rimon 10 EC), and its degradates for which toxicity data are available are not at levels of concern. These analyses are summarized below.

A definitive LC50 for marine fish was not determined for parent novaluron. However, the available toxicity data show no mortality and no signs of toxicity at the highest concentration tested (NOAEC 2 ug/L), a value close to but not exceeding the reported solubility limit of novaluron. For exposure scenarios involving cotton and potatoes, acute water concentrations are well below this NOAEC and so there is not a concern for acute effects. In contrast, the estimated water concentrations associated with the apples application scenario exceeds the available NOAEC. Because there are no available measurements of potential effects at higher novaluron concentrations, the available toxicity endpoints for estuarine/marine fish are insufficient to provide an RQ that could be compared with Agency concern levels to define the extent of the acute risks for the surface water concentrations estimated for the apple scenario. It is important to note that the peak water concentration estimated for the apple scenario is above the likely water solubility of novaluron (an artifact of the use of solubility information in the water models). The facts that (1) the NOAEC is so close to the solubility limit and (2) the apple scenario modeled surface water concentrations may actually exceed the solubility of novaluron suggest that concern for significant acute estuarine/marine risks for the apple scenario are remote.

An acute freshwater fish toxicity classification (toxic, highly toxic, very highly toxic, etc.) for novaluron cannot be definitively established because available acute toxicity data (MRID 45499004) do not establish an LC50 (the endpoint critical to classification). However, the available data for parent novaluron do establish an acute NOAEC (no observed mortality nor signs of intoxication) at the highest concentration tested 960 ug/L. It should be noted that this acute NOAEC of 960 ug/L is orders of magnitude greater than the water solubility of novaluron (3 ug/L). Combining the results of the existing toxicity data with the likely solubility limit of parent novaluron suggests that the compound is not acutely toxic to freshwater fish at the limit of the compound's solubility in water. A comparison of the NOAEC from this study with estimated surface water concentrations (Appendix E) confirms the assertion that surface water exposure would be well below levels that would trigger concern for acute risks to freshwater fish.

Toxicity data were submitted for the formulated product Rimon 10 EC, which indicted that the LC_{50} is 62,400 μg product/L for freshwater fish. Because typical aquatic modeling scenarios such as PRZM/EXAMS do not model formulated products, this acute formulated product fish toxicity endpoint was used in a separate assessment of formulated product drift risks. The LC50 value for Rimon 10EC was compared to surface water concentrations based on 1% and 5% drift assumptions (ground and aerial applications) of Rimon 10 EC to a standard surface water body (20 million liters). The resulting RQs (Appendix E) were all substantially below levels of concern ($<10^{-4}$) and even higher assumption of drift would be insufficient to yield water concentrations of formulated product that equal or exceed acute risk concern levels.

Additional long-term novaluron mortality data on the formulated product were available for freshwater fish. The LC50 from a 28-day study for freshwater fish was 7140 μg-formulated product/L. A comparison of this toxicity endpoint with the surface water drift concentrations also indicated that exposure estimates are well below concern levels for acute mortality.

The freshwater fish LC50 for chlorophenyl urea degradate (275351 I) is 530 μg /L. Comparisons of this toxicity value with GENEEC estimates for degradate concentrations in water (Appendix E) yielded risk quotients for freshwater fish well below all levels of concern.

Valid chronic freshwater fish toxicity data were submitted for parent novaluron. Chronic risk estimates for freshwater fish are below chronic levels of concern (Appendix E). No fish marine/estuarine chronic data were submitted for parent novaluron, the formulated product, or the chlorophenyl urea degradate. As a result, risk quotients cannot be estimated for these organisms. Extrapolation from freshwater chronic responses to estuarine/marine responses is possible and would suggest that estuarine/marine fish would not be at chronic risk if sensitivities were similar. However such an assertion would be quite uncertain, given that no common fish toxicity endpoints are available that enable establishment of a quantifiable a taxonomic sensitivity factor between the two broad fish categories.

Aquatic Plants

Aquatic plant risk to non-vascular plants was evaluated based on the marine diatom study (*Selenastrum capricornatum*) on parent novaluron, the formulated product, and the chlorophenyl urea. Vascular plant risk was based on the duckweed (*Lemna gibba*) which was performed solely on the formulated product. No acute non-endangered or endangered species LOCs were exceeded for the species tested (Appendix E).

Risks to Piscivorus Wildlife

The screening-level risk assessment commonly does not address aquatic food chain exposures and attendant risks to wildlife consuming aquatic organisms. However, the high bioconcentration (BCF) potential for novaluron is such that the potential for food chain exposure to be a risk for piscivorus wildlife should be explored. To do so, EFED used the peak, 21-day and 60-day EECs and the measured BCF for whole bluegill sunfish (14,431) to derive a suite of potential fish concentrations for each labeled use that could, in turn, be compared to dietary acute and chronic effects thresholds. The following presents the results of this comparison:

Use Site	EEC (mg/L)	Estimated Fish Concentration (mg/kg)	Fish Concentration/Chronic Threshold	
			Birds	Mammals
Pome Fruit	Peak - 0.005	72	7.3	<1
	21-day - 0.0032	46	4.7	<1
	60-day - 0.0022	32	3.3	<1
Cotton(aerial)	Peak - 0.0016	23	2.3	<1
	21-day - 0.0009	13	1.3	<1
	60-day - 0.0006	9	0.9	<1
Potato(aerial)	Peak - 0.0011	16	1.6	<1
	21-day - 0.0008	12	1.2	<1
	60-day - 0.0005	7	0.7	<1

Where: Fish concentration = EEC X BCF = EEC X 14,431
Bird Chronic toxicity threshold = 9.8 mg/kg diet
Mammal chronic toxicity threshold = 1000 mg/kg diet

This analysis suggests that, in all cases that EECs averaged over shorter periods may potentially result in whole fish novaluron concentrations that would exceed chronic toxicity thresholds for birds but not mammals. Longer averaging times for EECs, result in lower estimated water concentrations, and, in the case of cotton and potato uses, may result in fish concentrations of novaluron below chronic toxicity thresholds for birds and mammals. The available bioconcentration data for bluegill sunfish show that peak novaluron residues were reached by 35 days of exposure, suggesting that averaging times for novaluron in surface waters between 21-days and 60 days may be the most appropriate for estimating bioconcentration potential. The EECs and corresponding whole fish novaluron estimates for these averaging times straddle the chronic toxicity threshold in birds. Other bioconcentration estimates in other fish (e.g., rainbow trout) are not as high as those observed for bluegill sunfish. These other BCFs are an order of magnitude below the bluegill sunfish BCF, and if they are used to predict fish concentration of novaluron from EECs, the whole fish estimated novaluron concentrations would be well below the avian chronic toxicity threshold. On the basis of this preliminary analysis, there appears to be a potential concern for risks to piscivorus birds, but the extent to which this route is toxicological concern is uncertain across potentially exposed aquatic systems and for differing patterns of novaluron residues in surface waters. Differences in species BCF, and patterns of water concentration decline are important factors in the analysis. Monitoring of fish concentrations of novaluron under field use conditions would provide data important for further evaluation of the significance of this exposure route.

Risk to Birds

Acute Risks - Birds

Acute risk to birds utilizes exposure data from Hoeger and Kenaga (1972) as modified by Fletcher et. al. (1994), which determines residue levels on various terrestrial food items following an application in the field. Predicted maximum and mean residue levels are determined based on an application of 1 lb a.i./A on short grass, tall grass, broad-leaved plants/small insects, and seeds/large insects.

Toxicant concentrations on food items following multiple applications are predicted using a first-order residue decline method, EFED's "FATE5" model, which allows determination of residue dissipation over time incorporating degradation half-life. Predicted maximum and mean EECs resulting from multiple applications estimates the highest one-day residue, based on the maximum or mean initial EEC from the first application, the total number of applications, interval between applications, and a first-order degradation rate, consistent with EFED policy. The input parameters for the pome fruit scenario were based on a maximum single application of 0.32 lbs a.i./A with a maximum of 3 applications per year and a 10 day interval between applications. The input parameters for the cotton scenario were a maximum single application of 0.09 lbs a.i./A 3 times per year with a 7 day interval between applications. Parameters used for the potato scenario were based on a single maximum application rate of 0.78 lbs a.i./A 3 times per year at minimum intervals of 10 days between applications. Initially, all the above scenarios used the 35 day foliar dissipation half-life since limited data was available on foliar half-life.

Acute data submitted for parent novaluron indicates that the dietary LC50s were greater than 5200 mg/kg-diet for bobwhite quail and greater than 5310 mg/kg-diet for mallard duck. The LD50s were greater than 2000 mg/kg-bw for both species. Since the results from both the dietary LC50 and the oral gavage LD50 classify novaluron as practically non-toxic to birds and the formulations are non-granular, the dietary LC50 for bobwhite quail was selected for risk quotient calculations.

The resulting risk quotients (Appendix E) showed that acute risk quotients at all sites were below all levels of concern from all use sites using the most sensitive LC50 of >5200 mg/kg-diet. The highest RQ of <0.04 was observed for birds foraging in short grass at the highest use site (pome fruit).

The risk quotient results from banded applications to cotton (Appendix E), based on a 6-inch band width and 30-inch row space indicated that the levels of concern are not exceeded for any bird weight classes except for the endangered species LOC for 15 gram birds when rates were not adjusted by band width. If the rates were adjusted for band width, the acute risks resulting from banded applications are below all levels of concern.

Chronic Risk - Birds

Chronic risks to birds were evaluated using a mallard duck NOAEC of 9.8 mg/kg-diet based on the reproductive effect of viable eggs set. Use of this endpoint triggered level of concern exceedances at all use sites with the exception of fruit, pod, seeds, and large insect food categories on cotton and potatoes (Appendix E). The risk quotients ranged from 0.3 to 19.5.

Since chronic risks to birds exceeded the chronic LOCs at most of the bird forage sites using a 35-day foliar dissipation half-life, chronic LOC exceedances were estimated if shorter foliar dissipation half-lives were likely. To justify the use of shorter dissipation half-lives, EFED reviewed available foliar dissipation half-life data from the Health Effects Division (HED).

Limited information was available from on foliar half-lives (MRID 456384-12, 456384-20). A cursory review of these DERs revealed that only a handful of data for cotton and pome fruit reported results for Time 0 thru study termination (45 days), and many of the trials reported only one measurement point. With one exception, the data were variable throughout the studies for those reporting more than one result due perhaps to the multiple applications applied over the study period. Data from the studies with sufficient data points suggest that a decline in residues over the 45 day period is rapid for food sources of non-target animals. However, the variability of concentrations (some later sampling points were higher than earlier sampling) limit estimation of reliable foliar half-lives. To investigate the importance of the issue of alternative foliar dissipation half-lives in the avian chronic risk assessment, EFED ran the FATE 5 model using 1 and 5-day half-lives to assess the foliar dissipation half-life required to reduce chronic avian risk quotients below LOCs. Risk quotients for the additional FATE 5 analysis are presented in Appendix E. LOCs are exceeded for all crops at all avian food sources (except the fruits, pods, seeds, and large insects) for the 5 day foliar half-life. These results are also true even if the foliar half-life is assumed to be 1 day (with the exception of the tall grass food source which would be below chronic LOCs). Because chronic risk quotients are still exceeded regardless of the foliar dissipation rate assumed, chronic avian risk is an issue for the proposed multiple applications uses of novaluron. However, because the consideration of alternative foliar dissipation half-lives has the potential to reduce the scope of food sources with novaluron residues of chronic risk concern, the availability of reliable foliar dissipation data may be important, should any refined species-specific risk assessments (e.g., listed bird species assessments) be performed that would specifically address dietary behavior contributions to risk.

Chronic risk was also evaluated for single applications for maximum Fletcher values for predicted maximum and mean residues (Appendix E). This resulted in risk quotients exceeding the chronic LOCs for all food categories except the fruit, pod, seed, and large insect category for maximum residues for all crops. These risk quotients ranged from 0.1 to 7. The chronic LOCs were exceeded for the short grass, tall grass, and broadleaf/forage plants and small insect categories only for pome fruit for mean residues. These risk quotients ranged from 1.2 to 2.3.

Given the scenarios discussed above for the evaluation of chronic risk, it is doubtful that chronic risk can be mitigated below the chronic LOCs without substantial modifications to the prosed label use rates, number of applications and intervals.

Risks to Mammals

Acute risks to mammals were evaluated using the rat LD50 of > 5000 mg/kg-bw. There were no acute exceedances of the LOCs (Appendix E). The 2-generation rat study with an NOAEC of 1000 mg/kg-bw was used to evaluate mammalian chronic risk. No LOCs were exceeded for any of the use sites, and there are no chronic risk issues.

Risks to Non-Target Insects

EFED currently does not estimate risk quotients for terrestrial non-target insects. Whenever an LD_{50} is < 11 µg/bee an appropriate label statement is required to protect foraging honeybees. The acute contact toxicity study to honeybees revealed a contact LD_{50} > 100 µg/bee for the technical novaluron and a contact LD_{50} >200 µg/bee for the Rimon 10EC product. This classifies novaluron (Rimon technical) and the formulated product as practically non-toxic to honeybees. However, additional non-target insect studies were submitted. These additional studies demonstrated adverse effects on brood development at all growth stages and significant effects on wasp and predatory mite populations. These effects demonstrate that beneficial non-target insects may be at risk, at least immediately after spray applications. Due to the conflicting conclusions of the available data, general risk to non-target beneficial insects is uncertain at this time across all species.

Risks to Terrestrial Plants

Since terrestrial plant testing is not required for pesticides other than herbicides except on a case-by-case basis (*e.g.*, labeling bears phytotoxicity warnings incident data or literature that demonstrate phytotoxicity), risk quotients for terrestrial plants were not calculated.

Endangered Species Assessment

The Agency's level of concern for endangered and threatened freshwater and marine invertebrates, marine fish, and birds is exceeded for the use of novaluron. The Agency recognizes that there are no Federally listed estuarine/marine invertebrates. The registrant must provide information on the proximity of Federally listed freshwater vascular plants, birds, mammals, and non-target terrestrial plants (there are no listed estuarine/marine invertebrates) to the novaluron use sites. This requirement may be satisfied in one of three ways: 1) having membership in the FIFRA Endangered Species Task Force (Pesticide Registration [PR] Notice 2000-2); 2) citing FIFRA Endangered Species Task Force data; or 3) independently producing these data, provided the information is of sufficient quality to meet FIFRA requirements. The information will be used by the OPP Endangered Species Protection Program to develop recommendations to avoid adverse effects to listed species.

The preliminary risk assessment for endangered species indicates that Novaluron exceeds the endangered species LOCs for the following combinations of analyzed uses and species:

- Modeled surface water concentrations of Novaluron for use on pome fruit, cotton, and potatoes, when compared to acute toxicity endpoints exceed the acute endangered species LOCs for freshwater and marine/estuarine invertebrates. However, there are currently no endangered estuarine/marine invertebrates. Acute toxicity endpoints for freshwater invertebrates were based on extrapolated toxicity values using the acute to chronic toxicity ratios of marine invertebrates and applied to available chronic endpoints for freshwater invertebrates. When the endpoints from the chronic studies are compared with surface water exposure estimates, the risk quotients exceed the endangered species LOC. Given the chitin inhibiting mechanism of novaluron EFED evaluated whether listed freshwater molluscs would be at risk. Available acute data for molluscs suggests that these organisms might be less sensitive than the daphnid, upon which freshwater RQs are calculated. However, the mollusc data are limited to a single species, and comparison of the acute toxicity endpoint for this species with available surface water modeling, still suggests that the listed species acute LOC would be exceeded. Consequently, there is little screening-level risk assessment information available to support excluding freshwater molluscs from concern.

- Use of novaluron on pome fruit, cotton, and potatoes indicate endangered LOC exceedances for marine fish. However the results are very uncertain because a definitive LC50 was not obtained.

- Use of novaluron on pome fruit, cotton, and potatoes indicate that chronic LOCs are exceeded for birds foraging in all food categories except the fruit, pods, seeds, and large insect categories.

- Use of novaluron applied on cotton in banded applications trigger endangered species risks for 15 g birds. These risks could be easily mitigated by reducing the use rates for banded applications.

- A consideration of the data on the bioconcentration of novaluron in fish suggested that piscivorus birds might be exposed to novaluron in the diet at concentrations of potential chronic concern. Consequently, listed piscivorus bird species cannot be excluded from concern, based on information available in this screening-level risk assessment.

- Given the broad spectrum mechanism of action of novaluron on insect taxa, and the demonstrated effects of novaluron on insect pollinators and other beneficial insects, concern of direct toxic effects on listed insects cannot be excluded by information available from the screening-level risk assessment.

- Given the potential for aquatic invertebrate community effects, indirect effects to listed fish and birds consuming such organisms cannot be excluded based on screening level assessment information.

Comparisons of county-level location data for listed species (birds, molluscs, crustaceans, fish, and insects) were compared with county-level information on crop production to identify any coarse overlaps of listed species with the proposed labeled uses of novaluron. This analysis was limited to those counties with 10 or more acres of land in production for the labeled crops. The following presents those results:

<u>State</u> <u>Number of Listed Organisms</u>

	Bird	Mollusc	Crustacean	Fish	Insect
Alabama	4*	39	1	11	–
Arizona	9*	1	–	15	–
Arkansas	3*	5	1	2	–
California	16*	1	8	28	20
Colorado	4*	–	–	5	1
Connecticut	3*	–	–	1	1
Delaware	1*	–	–	1	–
Florida	9*	6	1	3	1
Georgia	4*	15	–	8	1
Idaho	1*	6	–	6	–
Illinois	3*	3	1	1	2
Indiana	1*	9	–	–	2
Iowa	2*	3	–	1	–
Kansas	4*	–	–	4	1
Kentucky	2*	20	1	2	–
Louisiana	4*	1	–	2	–
Maine	3*	–	–	2	–
Maryland	1*	1	–	2	2
Massachusetts	4*	–	–	1	1
Michigan	3*	2	–	–	3
Minnesota	2*	2	–	–	1
Mississippi	5*	3	–	3	–
Missouri	3*	5	–	6	1
Nebraska	5*	–	–	2	–
Nevada	2*	–	–	19	1
New Hampshire	1*	1	–	–	1
New Jersey	3*	–	–	1	–
New Mexico	6*	–	–	11	–
New York	3*	2	–	1	1
North Carolina	4*	5	–	4	1
North Dakota	4*	–	–	5	–
Ohio	2*	5	–	1	1
Oklahoma	6*	2	–	4	1
Oregon	5*	–	–	20	2
Pennsylvania	2*	2	–	–	–
Rhode Island	2*	–	–	1	1
South Carolina	4*	–	–	1	–
South Dakota	4*	–	–	2	–
Tennessee	3*	27	1	9	–
Texas	12*	–	1	5	5
Utah	2*	–	–	8	–
Vermont	1*	1	–	–	–
Virginia 3*	18	2	5	1	
Washington	4*	–	–	15	–
West Virginia	1*	5	–	–	–
Wisconsin	3*	1	–	–	2

*include piscivorus birds

IV. Environmental Fate Assessment

The environmental fate assessment for novaluron is based on acceptable and supplemental environmental fate data. Novaluron is a chiral compound containing a racemic mixture of two enantiomers (R,S). The available environmental fate and ecological effects data on novaluron represents only the racemic mixture. Additional data on individual enantiomers may be required if the registrant chooses to develop isomeric enriched products of novaluron.

Novaluron is immobile and non-persistent in soil laboratory studies. However, it appears to be more persistent in some field studies under actual use conditions. Novaluron persistence in field soils may be partially explained by temperature effects on metabolism; greater persistence is expected in cooler climates. Laboratory studies suggest that novaluron's major route of disappearance is microbially-mediated degradation. The chemical tends to strongly adsorb to soil and sediment, and it is stable to abiotic processes. Novaluron has a very low potential to reach ground water. During surface runoff conditions, novaluron may reach water bodies as bound to soil particles and will likely partition into sediments once in surface water. Additionally, contribution to surface water contamination may occur from spray drift.

Novaluron degradation rates in aerobic soil appear to be dependent on temperature. At 20 °C, novaluron metabolizes with half-lives from 7 to 14.5 days to form chlorophenyl urea (275-352I) and chloroaniline (MRIDs: 44961009 and 44961010). At 10 °C, novaluron degrades slower ($t_{1/2}$= 31.9 days) (MRID 44961009). In aquatic environments under stratified redox conditions (aerobic conditions in water and anaerobic conditions in soil) the chemical metabolizes with total system half-lives of 9.7 and 19.7 days (MRID 45638206). Under anaerobic conditions in water-soil systems, novaluron degrades slower with total system half-lives of 49 and 51 days (MRIDs: 45638205 and 45789203). A proposed transformation pathway in aquatic environments indicates novaluron forms 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl urea (275-352I) and 2,6-difluorobenzoic acid (275-158I, DFBA) through amide hydrolysis. Further hydrolysis of 275-352I yields 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline (275-309I) and hydrolysis of 275-158I yields 2,6-difluorobenzamide (275-157I) (MRID 5638206).

Novaluron was stable to hydrolysis at pH 5, 7, and 9 (pH 9 $t_{1/2}$ (25 °C) = 101 days; MRID 44961008) and stable to both soil and aqueous photolysis (soil photolysis $t_{1/2}$ = 257 days, MRID 45638204; aqueous photolysis $t_{1/2}$ = 187 days, MRID 45638203). At 50 °C in pH 9 buffer solution, however, novaluron appears to hydrolyze rapidly with a half-life of 1.2 days. Novaluron tends to adsorb strongly to soil and sediment. The mean simple K_d values ranged from 95 to 247 ml/g, and K_{oc} values from 6,650 to 11,813 (MRID 44961012). There was no linear relationship between the soil organic carbon content and the K_d values for different soils. Thus, the K_{oc} model may not be appropriate. Because novaluron was tested only at one concentration, Freundlich adsorption/desorption coefficients could not be calculated.

The high sorptive properties of novaluron indicate a low potential for leaching to ground water. In the field dissipation study conducted in North America, sites located in CA, LA, NY, WA, Nova Scotia, and Ontario, novaluron residues were not detected above 0.0851 ppm (Nova Scotia) in the 15-30 cm soil depth and above 0.0606 ppm (Ontario) in the 30-45 cm soil depths (MRID 45789204). In all sites, total water inputs (rainfall plus irrigation) were greater than the 10-year average rainfall except for the Nova Scotia site. Novaluron (RimOn 10EC) was not detected above the LOQ (10 ppb) at any sampling interval or in any replicate sample in the 10-20 cm soil depth when applied to bare soil in Spain and Germany (GLN 164-1; MRID 45638403). In these foreign studies pan evaporation data were not reported to assess whether sufficient moisture was present in the soil to facilitate leaching of the test substance. Irrigation was not applied to any of the test plots during the study trials and monthly rainfall data indicated that in the first 3 to 7 months rainfall was below historical average.

Novaluron (RimOn 10EC and RimOn 6.7WDG) dissipated with half-lives ranging from 20 to 178 days (i.e., in CA with a half-life of 20 days, in WA with a half-life of 61 days, in Nova Scotia with a half-life of 89 days, and in NY with a half-life of 178 days (valid $t_{1/2}$ could not be determined for the LA and Ontario sites)). There is, however, a great deal of uncertainty associated with the half-lives calculated at the NY and Nova Scotia sites due to high data variability, both between replicates and over time. In the field dissipation studies conducted in Spain and Germany, novaluron (RimOn 10EC) dissipated with half-lives ranging from 52 to 178 days (MRID 45638403). In five out of six sites in the North American field studies chlorophenyl (275-352I) urea was detected as a major transformation product (MRID 45789204).

In a microcosm study, novaluron exhibited water column DT_{90} values ranging from 12 to 20 days for three different test concentrations (i.e., 5, 15, and 50 g a.i./ha treatment level; MRID 45785801). Only low concentrations of novaluron were detected in sediment, demonstrating potential for microbial degradation. This was confirmed by the presence of the main degradate, chlorophenyl urea (275-352I), in the water column of three out of five tested concentration and in soil of the highest tested concentration. Chlorophenyl urea (275-352I) was the only degradate analyzed in water and sediment.

Novaluron appears to accumulate in edible and nonedible fish tissues. In a standard bioconcentration study using the bluegill sunfish, the highest mean bioconcentration factor (BCF) in whole fish was 14,431 x. The half-life for clearance of residues in the bluegill was 3.9 to 7.3 days for whole fish (MRID 45638215), suggesting that, while initial bioconcentration is high, changes in fish tissue would closely follow the dissipation pattern of novaluron in water.

The major novaluron degradate, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluorometh oxyethoxy) phenyl]urea (275-352I), was formed in aerobic soil metabolism at a maximum rate of 26.6% of the applied parent at 7 days posttreatment (MRID 44961009). Based on the McCall et al., 1980 classification system the degradate appears to have low to slight mobility in soil (K_{oc} values range from 1950 to 2563 L/kg; 163-1; MRID 45638201). The Freundlich isotherm, however, may not adequately represent adsorption of the compound across all concentrations (the 1/n values were not within the range of 0.9 to 1.1). Based on a laboratory study, novaluron degradates appear to have a very low potential for leaching into ground water. Chlorophenyl urea (275-352I) has the potential to reach surface water through runoff. Its aerobic soil metabolism half-lives estimated from the formation and decline curves (MRID 44961009) are 46.5 and 45.9 days. The degradate may be moderately persistent in the aquatic environment. The half-life was determined from the first-order degradation rate from the maximum concentration in the aerobic aquatic metabolism study (MRID 4538206). The aerobic aquatic metabolism half-life is 26.6 days in a Houghton Meadow water-loamy sand sediment.

Another novaluron degradate of potential concern is 3-chloro-4-(1,1,2-trifluoro-2-

trifluoromethoxyethoxy)aniline (chloroaniline, 275-309I) which was formed in the aerobic soil metabolism study at a maximum rate of 8.5% of the applied at 120 days posttreatment, the last sampling interval (MRID 44961009). Additionally, it is expected that chloroaniline is formed from the further degradation of the major degradate, chlorophenyl urea (275-352I) (MRIDs: 45638205 and 45789203). In the anaerobic aquatic metabolism study, at the last sampling interval, i.e., 363 days posttreatment, the maximum of 32% of the applied was formed in the soil and 49.8% in the total system. This includes soil and volatilized chloroaniline. This degradate has the potential to be volatile (i.e., its estimated vapor pressure exceeds 10^{-4} mmHg), more mobile (K_{oc} (an estimated value) = 5899) and more persistent than the parent. Degradation rates for chloroaniline could not be calculated due to the lack of formation and decline data.

V. Drinking Water Assessment Summary

Monitoring data for novaluron, chlorophenyl urea (275-352I) and chloroaniline in surface water and ground water were not found. Concentrations of novaluron and its degradates, chlorophenyl urea (275-352I) and chloroaniline in surface water and ground water were estimated via modeling.

Surface Water Assessment

A few crop scenarios were selected for novaluron Tier II PRZM-EXAMS modeling to provide high-end drinking water concentrations for each crop and represent the geographic locations where the specific crops are grown in large quantities. These scenarios are: apples in PA, NC and OR to represent the pome fruit group, cotton in MS, and potatoes in ME. The drinking water assessment was based on the maximum annual application rates on apples, cotton, and potatoes as specified on the labels.

The highest EECs were obtained for airblast application of novaluron to PA apples at the maximum annual application rate of 0.96 lbs a.i./acre, applied three times at 0.32 lbs a.i./acre with an interval between applications of ten days. Table 1 lists estimated drinking water concentrations from surface water sources for all modeled scenarios. For the modeling input parameters and modeling uncertainties refer to the Drinking Water Memorandum in Appendix A.

Table 1. Novaluron estimated drinking water concentrations for surface water sources.

Scenario	Application Type	Estimated Drinking Water Concentrations from Surface Water Sources (ppb)		
		1 in 10 year annual peak	1 in 10 year annual mean	36 year annual mean
PA apples (PCA = 0.87)	airblast	11.4*	1.8	1.2
NC apples (PCA = 0.87)	airblast	4.24*	0.60	0.38
OR apples (PCA = 0.87)	airblast	1.6	0.38	0.31
MS cotton (PCA = 0.20)	ground aerial	0.70 0.78	0.07 0.08	0.04 0.05
ME potato (PCA = 0.87)	ground aerial	2.15 2.43	0.38 0.45	0.24 0.32

*These values exceed the measured water solubility of novaluron of 3 µg/L (3 ppb).

The HED MARC concluded that parent, chlorophenyl urea (1 -[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy) phenyl] urea) (275-352I), and chloroaniline (3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline) are residues of potential concern to be included in the drinking water assessment hence a Tier I drinking water assessment was performed for these degradates. Chlorophenyl urea and chloroaniline scenarios were based on the following: (1) assuming 26.6% (MRID 44961009) conversion from parent to chlorophenyl urea (275-352I) and 100% conversion from parent to chloroaniline, and (2) using molecular weight conversion to adjust from parent application rate to the degradate application rate. Table 2 lists estimated drinking water concentrations for both degradates for all novaluron proposed maximum uses. For the modeling input parameters and more details on assumptions, and modeling uncertainties, refer to the Drinking Water Memorandum in Appendix A.

Table 2. Degradates' estimated drinking water concentrations for surface water sources based on Tier I modeling.

Novaluron Metabolite	Crop	Application Rate	Estimated Drinking Water Concentrations from Surface Water Sources (ppb)	
			Peak	Annual Average
chlorophenyl urea	apples:	3 X 0.32 lbs a.i./acre	4.56	0.86
	cotton	3 X 0.09 lbs a.i./acre	0.30	0.057
	potato	3 X 0.078 lbs a.i./acre	1.12	0.21
chloroaniline	apples	3 X 0.32 lbs a.i./acre	11.4	2.61
	cotton	3 X 0.09 lbs a.i./acre	0.75	0.17
	potato	3 X 0.078 lbs a.i./acre	2.80	0.64

Ground Water Assessment

SCI-GROW modeling predicted a ground water concentration for novaluron at the annual application rate of 0.96 lbs a.i./acre (i.e., three applications of 0.32 lb a.i./acre) of 5.5 x 10^{-3} µg/L in drinking water from shallow ground water sources. The predicted ground water concentration is 4.5 x 10^{-3} µg/L for chlorophenyl urea and 9.0 x 10^{-3} µg/L for chloroaniline from novaluron's maximum application rate (0.96 lbs a.i./acre). Both concentrations were estimated with the same assumption used for surface water modeling. These concentrations may be considered as both the peak and annual average upper bound exposures.

VI. Aquatic Hazard, Exposure, and Risk Quotient Calculation

Appendix C summarizes the results for toxicity studies material to this risk assessment. Discussions of the effects of novaluron, formulated product, and degradates on aquatic taxonomic groups are presented in the following sections.

Toxicity to Fish

An acute freshwater fish toxicity classification (toxic, highly toxic, very highly toxic, etc.) for novaluron cannot be definitively established because available acute toxicity data (MRID 45499004) do not establish an LC50 (the endpoint critical to classification). However, the available data for parent novaluron do establish an acute NOAEC (no observed mortality nor signs of intoxication) at the highest concentration tested 960 ug/L. It should be noted that this acute NOAEC of 960 ug/L is orders of magnitude greater than the water solubility of novaluron (3 ug/L). Combining the results of the existing toxicity data with the likely solubility limit of parent novaluron suggests that the compound is not acutely toxic to freshwater fish at the limit of the compound's solubility in water. A repeat of the acute fish toxicity test, conducted using methods to test above the solubility limit (a supersaturated system), might establish an LC50 for classification purposes, but would be of questionable utility in freshwater fish risk assessment.

An acute freshwater fish study submitted for the Rimon 10 EC formulated product indicted that the LC_{50} is 62,400 µg product/L (5,740 µg ai/L) for freshwater fish (MRID 456383-14). This endpoint is well in excess of the water solubility limit of novaluron. Three explanations for these observations are possible. First, novaluron itself is responsible for the acute toxicity observed in this study and the formulated product has resulted in a super saturated condition in the test system. This explanation is unlikely because the parent novaluron concentration is over 3 orders of magnitude higher than the solubility limit (a remarkable saturation not likely to be achieved); and systems with as much as 960 ug/L novaluron (discussed above) resulted in no toxic effects. Second, the toxicity observed in the study is the result of the inherent toxicity of constituents of the formulation other than novaluron, a possibility that cannot be dismissed because novaluron alone is of demonstrably low toxicity. Third, both novaluron and other formulation constituents are responsible for the observed toxicity, a hypothesis that available data cannot exclude. Because typical aquatic modeling scenarios such as PRZM/EXAMS do not model formulated products, this acute formulated product fish toxicity endpoint was used in a separate assessment of formulated product drift risks.

The acute novaluron LC_{50} for marine fish was not determined by available toxicity data (MRID 45638210). This lack of an LC50, precluded a toxicity classification of novaluron. However, the data do suggest that the NOAEC for novaluron is at least as high as the highest dose tested (2 ug/L), which is very close to the established solubility limit of the compound (3 ug/L). No sub-lethal effects were observed in this study. Because of the lack of a reported LOAEC, the NOAEC result from this study is uncertain. However, it is unlikely that a repeat of the study will generate an acute lethality endpoint consistent with screening risk assessment methods that would be at environmentally relevant concentrations. There are no data for either the formulated product or the metabolite.

A chronic toxicity study was submitted for freshwater fish early life-stage (rainbow trout) for parent novaluron. Although this study was not based on the EPA guideline specifications, it does provide useful information for assessing chronic risk. The NOAEC of the parent was 6.16 ug/L based on terminal growth and mortality (MRID 456382-16). Additionally, a chronic fish early life-stage test was submitted for the fathead minnow (MRID 456382-13), but was found to be invalid due to numerous deviations from the EPA protocol (most notably variations in stability measurements at all test levels).

A chronic full life cycle test was submitted for freshwater fish (fathead minnow) on the parent novaluron (MRID 457858-05), but was found to be invalid because adequate raw data pertaining to survival of both generations and growth of the F_0 generation was not provided to verify the results of the study. Additionally, several endpoints were not measured such as time to hatch for the F_0 and F_1 generations, lengths of the F_0 fish at 4 and 8 weeks post-hatch, and survival of F_0 fish at 4 weeks post-hatch. The measured NOAEC was 3 ug/L, and this study could be up-graded to supplemental status if the missing raw data were submitted.

Chronic freshwater fish toxicity testing was also submitted for the formulated product Rimon 10 EC (MRID 456384-06) and indicated a chronic NOAEC of 1210 μg formulated product/L (111.32 ug ai/L when adjusted to the percent active ingredient) and a 28-day survival LC_{50} of 7140 μg formulated product/L (660 ug ai/L adjusted). However, as with the case of acute testing of this formulated product, the novaluron active ingredient-based NOAEC is well in excess of the water solubility limit of the active ingredient. The potential explanations for this observation are similar to those discussed for the acute testing of the formulated product. Additionally, this study does not meet USEPA guideline requirements and cannot be used to calculate chronic risk quotients because this test was initiated with 5-month-old juvenile rainbow trout. The USEPA fish early life stage test requires that the test be initiated with fish embryos and terminate at swim-up. No chronic data was submitted for marine fish.

Toxicity to Aquatic Invertebrates

Parent Compound (Novaluron)

Acute freshwater invertebrate data for parent novaluron has been classified as invalid due to the high variability of the measured concentrations during the test (MRID 454768-02). A valid acute toxicity test will be required to properly address the risk.

Chronic studies were also available for freshwater and marine invertebrates with the technical grade of the active ingredient. These data demonstrate that both the daphnid and the mysid shrimp are very sensitive to novaluron. The NOAEC of 0.0299 ug/L for the daphnid was based on survival of the parents and the production of offspring (MRID 456382-11). The most sensitive endpoint for the mysid shrimp was for reductions in the terminal male body length, with an NOAEC of 0.026 ug/L (MRID 456382-12).

Formulated Product (Rimon 10 EC)

Acute aquatic invertebrate data are also available for the formulated product Rimon 10 EC for freshwater invertebrates (MRID 456383-13). Data for Rimon 10 EC indicates that the EC_{50} is 4.31 ug/L (0.4 ug ai/L when adjusted to the percent active ingredient) and very highly toxic to freshwater aquatic invertebrates. However, as discussed above for fish, there may some uncertainty with these results since it appears that the measured concentrations were not centrifuged as required under the current EPA pesticide Reregistration Rejection Rate Analysis. This may account for the higher measured concentrations (hence, lower toxicity) in the water column. There is uncertainty with regards to the contribution of novaluron to the toxicity of this study. This uncertainty could be reduced if a valid study for parent novaluron was submitted. Therefore, a valid toxicity test will be required for the parent novaluron.

In the absence of a valid acute toxicity test for freshwater invertebrates the ratios of the acute to chronic toxicities were assumed to be the same as those for marine invertebrates. The following equation was used to derive an estimated acute LC_{50} of 0.15 µg ai/L for freshwater invertebrates.

$$\textbf{\textit{Acute toxicity}}_{fw} = \textbf{\textit{Chronic toxicity}}_{fw}\ \textbf{\textit{x Acute toxicity}}_{est} / \textbf{\textit{Chronic toxicity}}_{est}$$

The 275-352 I degradate of Novaluron is practically non-toxic to freshwater invertebrates (EC_{50} = 1910 ug/L) (MRID 454990-07).

Marine aquatic data on the technical grade of the active ingredient indicate that novaluron is very highly toxic to shrimp (MRID 456382-09) and oyster (MRID 456382-08) (LC_{50} =0.13 and 1.5 ug/L respectively). Additional acute data on the formulated product Rimon 10 EC (460862-03) demonstrate that novaluron is very highly toxic to shrimp (LC_{50} = 0.12 ug ai/L). No data are available for the major degradate chlorophenyl urea (275-352 I) for marine invertebrates. Such data might help to better characterize the risk and reduce associated uncertainties.

Toxicity to Aquatic Plants

Tier 1 Aquatic plant testing was conducted for the marine diatom *Selenastrum capricornutum* and found that the EC_{50} for cell density was >9,680 µg ai/L (MRID # 456382-21).

A Tier 2 study of *Selenastrum capricornutum* for the 275-352 I metabolite revealed an EC_{50} of 330 ug/L based on cell density (MRID # 456382-22). Further testing of the formulated product indicated that the EC_{50} of 39000 ug ai/L for the same alga (MRID 456384-11). Further tier 2 formulated product testing of the vascular plant *Lemna gibba* (duckweed) indicated an EC_{50} based on biomass of 777 ug ai/L (MRID 456382-23).

Community Effects Studies

A microcosm study involving a community of selected algae and aquatic invertebrates was submitted for review (MRID 458858-01). The principle objectives of the study was to assess the potential biological effects of novaluron in invertebrate communities and define the no effect concentration and ecologically acceptable concentration (EAC; µg ai/L). No fish were included in the community structure.

Duplicate microcosm chambers were dosed with 0.05, 0.15, 0.5, 1.5, or 5 µg/L of novaluron (initial nominal application) in the form of Rimon 10 EC. Applications were made twice to each chamber, with a 14-day application interval.

Water concentrations were measured immediately after application (periodically thereafter to 84 days after initial application) from samples collected at 10 and 45 cm depth. Initial measurements confirmed the nominal application rates. The mean times for 90% disappearance (DT_{90}) at 0.5 and 1.5 µg/L subsequent to the second application were 18 and 12 days, respectively. It is important to note that the nominally exposed chambers at 5 µg/L exhibited measured initial concentrations of novaluron in excess of the solubility limit. Because the samples were unfiltered collections, measured concentrations in excess of solubility may reflect a combination of dissolved and colloidal/particulate associated novaluron in the water column.

Sediment (upper 1 cm) concentrations of novaluron were measured starting 3 days after application with periodic sampling events extending out 84 days after initial pesticide application. Novaluron was not detected in sediment (detection limit 5 ng/g) in the two lowest doses, novaluron was detected in only two sediment samples (max 10 ng/g at day 35) at the 0.5 µg/L dose. Peak sediment concentrations of novaluron were 24 ng/g (14 days after 2nd application) and 72 ng/g (35 days after 2nd application) for the 1.5 µg/L and 5 µg/L dose levels, respectively.

Primary production measurement endpoints consisted of phytoplankton chlorophyll a and phaeophytin levels, periphyton biomass, and mascrophyte species counts. Chlorophyll-a levels were elevated post application for the three highest dose groups, with peak chlorophyll a concentrations 28 days after the first application (14-days after 2nd application).

Zooplankton measurements included measures of taxa numbers, initially at the family level with a subsequent analysis of discrete genera and species for those organisms defining system response to novaluron. In general, total measured zooplankton populations exhibited negative responses to novaluron, as compared to controls for all dose levels, with statistically significant population reductions ($p<0.01$) at the 0.15 though 5 ug/L dose levels. Individual taxonomic family responses are summarized as follows:

Taxa	**NOAEC for Population Reductions ug/L**
Chydoridae	0.15 (day 84)
Cyclopoidae	<0.05 (recovery after 84 days at this dose level)
Nauplii	<0.05 (recovery after 84 days at this dose level)
Synchaetidae	0.5 (day 84)
Daphnidae	> 5.0 (significant reductions in 2nd phase)

Lecanidae	1.5 (significant increases in numbers at day 84)
Brachionidae	5.0 (significant increases in numbers at day 84)
Chaoboridae	<0.05 (day 42, recovery by day 70)
Chirocephalidae	<0.05 (day 56)
Diaptomidae	0.15 (day 56)

Analyses of benthic invertebrate populations were conducted primarily at the family level, with subsequent analysis to more refined taxonomic levels for those organisms showing definitive responses to novaluron treatment. Analysis of benthic invertebrate community response (taxonomic response weighting) shows statistically significant ($p<0.05$) community level effects at the 0.15 ug/L dose level, with a community level response NOAEC of 0.05 ug/L. It should be noted that the Gammaridea showed statistically adverse response ($p<0.01$) below that observed for the community as whole, with an NOAEC <0.05 and complete eradication of the family at all dose groups by study termination.

It is important to realize that all NOAEC's from this study are presented in terms of the initial nominal novaluron concentration. However, many of the effects observed in the study progress over considerable time periods following initial novaluron application. Concurrent with the emergence of observable effects over the course of the study, measurements of water column concentrations of novaluron are declining with time. Consequently the study cannot provide definitive information on the actual water concentration over time that can be associated with an observed adverse effect. Reliance on the nominal concentrations for establishment of NOAECs likely underestimates the toxic potential of novaluron.

Aquatic Exposure

Tier II modeling (PRZM 3.12 and EXAMS 2.975 coupled with a graphical interface shell, the PE4V01.pl program dated 8/8/2003) was used to estimate the concentrations of novaluron in surface water from the proposed food uses. For the purpose of the modeling, the maximum annual application rate, maximum number of applications per season, and the minimum intervals between the applications were selected to estimate the aquatic exposure concentrations. The crop scenarios were selected to provide high-end exposures for aquatic EECs for each crop and represent the geographic locations where the specific crops are grown in large quantities. The scenarios that were modeled are Pennsylvania apples (airblast application), Mississippi cotton (ground and aerial application), and Maine potato (ground and aerial application). The input parameters used for the aquatic exposure modeling are provided in Tables 3 and 4. The output files for aquatic exposure modeling are provided in Appendix B.

Table 3. Environmental Fate and Chemistry Input Parameters for Novaluron

Parameters	Input Value and Unit	Source of Info/Reference
Maximum Application Rates [1]	apples = 0.359 kg ai/ha cotton = 0.100 kg ai/ha potato = 0.087 kg ai/ha	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35 (?)
Maximum Number of Applications	apples = 3 cotton = 3 potato = 3	Product Labels as above
Minimum Interval Between Applications	apples = 10 days cotton = 7 days potato = 10 days	Product Labels as above
Soil Partition Coefficient (K_d)[2]	133	MRID 44961012
Molecular Weight	492.7	Registrant data
Solubility (at 25 °C) x 100	0.3 ppm	Registrant data (MRID 45638203)
Vapor Pressure	1.2×10^{-7} mm Hg	Registrant data
Henry's Constant at 25 °C	1.974×10^{-13} atm•m³/mol	Registrant data
Aerobic Soil Metabolism $T_{1/2}$[3]	15.6 days	MRIDs: 44961009 and 44961010
Foliar Dissipation $T_{1/2}$	-	was not considered in the modeling
Aqueous Photolysis (pH 5) $T_{1/2}$[4]	187 days	MRID 45638203
Hydrolysis $T_{1/2}$ (pH7)	stable	MRID 44961008
Aerobic Aquatic Metabolism Half-life[5]	30.1 days	MRID 45638206
Anaerobic Aquatic Metabolism Half-life[5]	52.1 days	MRIDs: 45638205 and 45789203

[1] - One planting per year was assumed and the annual rate is assumed to be the seasonal rate

[2] - The lowest non-sand K_d for sandy loam with sand content < 70% was used. Out of four K_f values (133, 247, 184, and 95) the lowest non-sand K_f
for sandy loam was used (K_{oc} model was not valid).

[3] solubility was adjusted to 0.3 ppm for Tier II modeling according to EFED input parameter guidance.

[4] - Since n=4: to account for the inherent variability the constant rate of the upper confidence bound on the mean (mean half-life (of 14.5, 13.7, 7, and 11.5) + (t_{90} σ)/$\sqrt{n}$ (single tail student's t, α=0.1 where n = number of values)) aerobic soil metabolism half-life was used

[5] - individual data points were very variable so the accuracy of the half-life is uncertain

[6] - since n=2 (aerobic $T_{1/2}$: 19.7 and 9.7 days; anaerobic $T_{1/2}$: 50.6 and 49.2 days), the upper confidence bound on the mean aquatic metabolism half-life was used.

Table 4. Additional PRZM-EXAM Input Parameters for Pond Scenario for Novaluron

Parameters	Input Value and Unit	Source of Info/Reference
First Application Date (day-month)	apples = PA: 25-07 cotton = 20-07 potato = 15-06	assumed based on crop profiles and probable target insect infestation
Rainfall Data (Metfile)	apples = PA: W14737.dvf cotton = MS: W03940.dvf potato = ME: W14607.dvf	Individual crops' scenarios
Application Fraction	apples airblast = 0.99 cotton & potato aerial = 0.95 cotton & potato ground = 0.99	Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Feb. 28, 2002
Spray Drift Fraction	apples airblast = 0.01 cotton & potato aerial = 0.05 cotton & potato ground = 0.01	as above

The one in 10 year concentrations for acute peak, 21-, 60-, and 90-days and for annual durations are provided in Table 5.

Table 5. PRZM/EXAMS Estimated EECs for Novaluron - Aquatic Exposure

Crops or Crop Groups and Application Information	One in Ten Year Surface Water Concentrations (ppb)				
	Peak	21 days	60 days	90 days	Yearly
Apples in PA (airblast, 0.32 lb/acre, 3x, 10 days)	5.04	3.18	2.24	1.93	0.77
Cotton in MS (aerial, 0.09 lb/acre, 3x, 7 days)	1.58	0.93	0.62	0.51	0.19
Cotton in MS (ground, 0.09 lb/acre, 3x, 7 days)	1.39	0.85	0.52	0.43	0.16
Potato in ME (aerial, 0.078 lb/acre, 3x, 10 days)	1.09	0.78	0.54	0.45	0.21
Potato in ME (ground, 0.078 lb/acre, 3x, 10 days)	0.94	0.65	0.43	0.36	0.16

Exposure issues associated with the formulated product were addressed assuming exposure through spray drift alone. This exposure assessment assumes the impact of the formulated product from runoff on aquatic exposure would be negligible due to microbial degradation and soil sorption of the formulated product. Therefore, the exposure scenario assumes 5% drift of the formulated product into the standard pond would yield the highest concentration of the formulated product. Estimated concentrations are provided in the table below.

Table 6. Estimated Environmental Concentrations from Direct Applications of Rimon 10EC to Surface Water

Crop	Application Rate (lb ai/A)	Percent Active Ingredient	Application Rate of Formulated Product (lb/A)	Mass of drifted Formulated Product (mg)	Conc. of Formulated Product (ug/L) in Farm Pond
Pome fruit	0.32	0.092	3.478	78956.5	3.95
Cotton	0.09	0.092	0.9783	22206.5	1.11
Potato	0.078	0.092	0.8478	19245.65	0.96

Additionally, for the degradate chlorophenyl urea Tier I drinking water analysis was performed. For the surface water modeling the GENEEC model was used as if chlorophenyl urea was "granular" applied to the field with no spray drift and no foliar interception. The degradate scenario was based on the following: (1) assuming 26.6% (MRID 44961009) conversion from parent to chlorophenyl urea and (2) using molecular weight conversion to adjust from parent application rate to chlorophenyl urea application rate. Table 7 lists GENEEC input parameters for the degradate.

Table 7. GENEEC Input Parameters for 1-[3-Chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]urea

Parameters	Input Value and Unit	Source of Info/Reference
Maximum Application Rates [1]	apples = 0.061 lb/acre cotton = 0.017 lb/acre potato = 0.015 lb/acre	$rate_{der} = rate_{par} * (MW_{deg}/MW_{par}) *$ (max. % form. rate/100)
Maximum Number of Applications	apples = 3 cotton = 3 potato = 3	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35
Minimum interval between applications	apples = 10 days cotton = 7 days potato = 10 days	Product Labels as above
Soil Partition Coefficient (K_d)[2]	16.7	MRID 45638201 (GLN 163-1)
Aerobic Soil Metabolism $T_{1/2}$[3]	47.1 days	MRID 44961009
Wetted in	No	Product Label
Depth of incorporation (inches)	0	Product Label
Method of application	granular	assumed; a degradate formed in soil
Solubility in water at 20 °C	33 ppm	MRID 45638201
Aerobic aquatic metabolism half-life[4]	26.6 days	MRID 45638206
Aqueous Photolysis (pH 5) $T_{1/2}$	stable	assumed; data not available

[1] – Application rate of 275-352I is based on the maximum formation rate of 26.6 % from parent novaluron found in the aerobic soil metabolism study (MIRD 44961009) and molecular weigh conversion (MW_{par} = 492.7; MW_{deg} = 352.6).
[2] - the lowest non-sand K_f (sandy loam) was used. Out of four K_f values (35.1; 16.7; 61.5; and 47.6) the lowest non-sand K_f for sandy loam was used (K_f may not equal K_d).
[3] - 275-352I first order non-linear half-lives were estimated from formation and decline curves using the maximum concentration as the initial concentration; since there were two valid half-lives estimated, i.e. 46.5 and 45.9 days, therefore the upper confidence bound on the mean metabolism half-life was used as the model input value.
[4] - a first order non-linear half-life was calculated from formation and decline curve using the maximum concentration as the initial concentration;

The aquatic EECs for 275-352I are provided in Table 8. The output files for aquatic exposure modeling for the degradate are provided in Appendix B.

Table 8. GENEEC Estimated EECs for 275-352I - Aquatic Exposure

Crop	Aquatic EECs in ppb				
	Peak	4 days	21 days	60 days	90 days
Apples	2.39	2.33	2.00	1.47	1.19
Cotton	0.69	0.67	0.58	0.43	0.34
Potato	0.59	0.57	0.49	0.36	0.29

Risk Quotients

The methodology for calculating RQs is presented in Appendix D. The resulting RQs for the parent toxicity values are presented in detail in Appendix E.

VI. Terrestrial Hazard, Exposure, and Risk Quotient Calculation

Appendix C provides tabular summaries of the toxicity studies material to the risk assessment for novaluron. The toxicity of novaluron, formulated products, and degradates are discussed below for each terrestrial taxonomic group studied.

Toxicity to Birds

Acute testing through oral gavage of technical Novaluron (GR 572) to bobwhite quail and mallard duck indicates that the LD_{50} is > 2000 mg/kg-body weight. The dietary LC_{50} for both species is > 5200 mg/kg-diet. No sub-lethal effects or other treatment related effects were observed in any of these studies with the exception of the bobwhite dietary study (MRID 454990-02) which recorded two mortalities in the 5200 mg a.i./kg treatment group, while body weight and food consumption were not affected by treatment. This classifies technical novaluron as practically non-toxic to birds. Details of the results are tabulated in Appendix C.

Chronic testing of Rimon technical to the bobwhite quail indicates an NOEAC of 301 mg/kg-diet based on the number of viable and live embryos, the number of hatchlings/hen, the number of 14 day old survivors/hen, and the number of 14-day old survivors of hatchlings. Test results from Rimon technical indicates that the mallard duck is more sensitive then the bobwhite quail. The mallard duck NOEAC is 9.8 mg/kg-diet based on the number of viable embryos/pen and viable 14-day embryos of eggs set.

Toxicity to Mammals

Acute testing through oral gavage of technical Novaluron (GR 572) to laboratory rats indicates that the LD_{50} is > 5000 mg/kg-body weight. This classifies the technical novaluron as practically non-toxic to birds. Data were not submitted for the major chlorophenyl urea (275 352 I).

For chronic mammalian testing the two generation rat or mouse studies, and/or the developmental rabbit study are more relevant than the longer term mammalian carcinogenicity/oncogenicity studies. Accordingly, EFED has obtained the rat two generation rat toxicity study for the novaluron technical (GR 572). The results from the two generation rat study indicate an NOEAC of 1000 mg/kg-diet (72.4 mg/kg bw/da) based on the epididymal sperm counts in the male F_1 generation. The reproductive NOAEL in females was$\geq$12,000 ppm (1009.8 mg/kg bw/day). In addition, the parental systemic LOAEL was 1000 ppm (74.2 mg/kg bw/day in males, 84.0 mg/kg bw/day in females), based on increased absolute and relative spleen weights. Finally, the offspring LOAEL was 1000 ppm (74.2 mg/kg bw/day in males, 84.0 mg/kg bw/day in females), based on increased absolute and relative spleen weights. The parental offspring NOAELs were not identified.

Toxicity to Non-target Insects

An acute contact toxicity study to honeybees revealed a contact $LD_{50} > 100$ µg/bee. This classifies novaluron (Rimon technical) as practically non-toxic to non-target insects. However, three other non-target insect studies were submitted.

Honeybee hives fed sucrose solutions containing RIMON 10E C 3.3 (ml/L) showed significant ($p<0.05$) adverse effects on honey bee brood development at the egg, young larvae, and old larvae developmental stages(MRID # 456384-07). Overall failure rate of eggs in Rimon-treated hives was more that twice that of controls (100% failure for Rimon 10 EC treatment vs 49 % for control). Young larvae failure in Rimon-treated hives was almost 3 times that of controls (98% failure for Rimon 10 EC treatment vs 39% for control). Old larvae failure for Rimon-treated hives was 4 times greater than controls (79% failure for Rimon 10 EC treatment vs 19 % for control). The Rimon 10 EC dose was selected to represent the field application rate for the formulated product under field conditions. For comparison, review of the product labels for this risk assessment indicate that 14.4 ml/L Rimon 10 EC in the spray volume is the maximum formulated product concentration in spray.

A field study was conducted to evaluate the effects of Rimon 10 EC on honeybee application to citrus groves in Israel(MRID 45638409). The formulated product was applied at a rate equivalent to 0.2 lb/acre twice with an interval of 7 days. Applications were made during grove flowering. Bee hives were located within the test plots. Honeybee brood development was significantly impaired ($p<0.05$) at the egg, young larvae, and old larvae stages following the first application of pesticide. However, in cases where the hive subsequently removed the affected eggs of larvae, new eggs had been laid and this second generation proceeded with normal development. Removal of hives after the test period and subsequent analysis of hive status over a further month showed no residual impairment of hive foraging activity nor adverse effects on the number of bees.

A field study designed to assess the impact of Rimon 10 EC on non-target arthropod insect populations in citrus groves in Sicily was submitted. Two applications were made at an interval of 7 days when oranges were reaching the end of flowering and the fruit was beginning to set. The organophosphate, diazinon was applied at sampling intervals to kill and collect all arthropods present by drop-net sampling. In addition, a control treatment of water, an IGR reference product (Cascade 50 DC) applied at 150 ml product/hL, and a conventional insecticide standard (Danitol) applied at a rate of 75 ml product/hL. Three plots of trees were treated for water control and Rimon 10 EC treatments. One plot was used for each of the Cascade 50 DC and Danitol treatments. Each plot consisted of 7 rows of 8 trees with 6m row spacing. The plots were separated by 1 row of untreated trees. Sampling methods consisted of drop netting to collect arboreal invertebrate fauna, and samples were taken one day before the first application and on days 0, 1, 2, 4, 6, 7, 9, 11, 13, 28, 42, 70, 99, and 176. At regular intervals up to 176 days after leaf inspection, aphid parasitoid sampling, and pitfall traps showed significant effects on wasp and predatory mite populations, however, complete recovery occurred within two days and 2 months, respectively, after the second application (MRID # 456384-10). No other effects were observed in any of the other taxa collected throughout the study.

Toxicity to Earthworms

Acute toxicity studies to earthworms (*Fisenia foetida*) in accordance with OECD guidelines were performed for the Rimon technical novaluron and the degradate chlorophenyl urea (MRID# 456382-24 and 456382-25). The LC_{50} of the technical and the chlorophenyl urea degradate is >1000 and 447 mg/kg respectively. No sub-lethal effects were observed in these studies.

Toxicity to Non-target Plants

Terrestrial plant testing (seedling emergence and vegetative vigor) is required for herbicides that have terrestrial non-residential outdoor use patterns and that may move off the application site through volatilization (vapor pressure $>1.0 \times 10^{-5}$mm Hg at 25°C) or drift (aerial or irrigation) and/or that may have endangered or threatened plant species associated with the application site. Currently, terrestrial plant testing is not required for pesticides other than herbicides except on a case-by-case basis (*e.g.*, labeling bears phytotoxicity warnings incident data or literature that demonstrate phytotoxicity). Since novaluron is a new chemical insecticide and meets none of the above criteria, data will not be required at this time.

Exposure

Terrestrial exposure estimations differ for the groups of terrestrial organisms. One major difference in the way in which exposure scenarios are evaluated for terrestrial species is the methodology used for non-granular and granular applications. Since the proposed uses for novaluron is limited to a water dispersible granular and an emulsifiable concentrate, exposure scenarios were only considered for non-granular applications.

Birds and Mammals

Toxicant concentrations on terrestrial food items are based on data from by Hoerger and Kenaga (1972) as modified by Fletcher et al. (1994) that determined residue levels on various terrestrial items immediately following toxicant application in the field. These values are summarized in the table below.

Estimated Environmental Concentrations on Avian and Mammalian Food Items (ppm) Following a Single Application at 1 lb ai/A)

Food Items	EEC (ppm) Predicted Maximum Residue[1]	EEC (ppm) Predicted Mean Residue[1]
Short grass	240	85
Tall grass	110	36
Broadleaf/forage plants and small insects	135	45
Fruits, pods, seeds, and large insects	15	7

[1] Predicted maximum and mean residues are for a 1 lb ai/a application rate and are based on Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

Toxicant concentrations on food items following multiple applications are predicted using a first-order residue decline method, EFED's "FATE5" model, which allows determination of residue dissipation over time incorporating a degradation half-life. Predicted maximum and mean EECs resulting from multiple applications estimates the highest one-day residue, based on the maximum or mean initial EEC from the first application, the total number of applications, interval between applications, and a first-order degradation rate, consistent with EFED policy. The input parameters for the pome fruit scenario were based on a maximum single application of 0.32 lbs a.i./A with a maximum of 3 applications per year and a 10 day interval between applications. The input parameters for the cotton scenario was a maximum single application of 0.09 lbd a.i./A applied 3 times per year with a 7 day interval between applications. Parameters used for the potato scenario were based on a single maximum application rate of 0.78 lbs a.i./A applied 3 times per year at minimum intervals of 10 days between applications. Initially, all the above scenarios used the 35 day foliar dissipation half-life since limited data were available on foliar residue studies.

Dietary exposure to mammals from liquid sprays is based upon EFED's draft 1995 SOP for mammalian risk assessments and methods used by Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994). The concentration of novaluron in the diet that is expected to be acutely lethal to 50% of the test population (LC_{50}) is determined by dividing the LD_{50} value (usually a rat LD_{50}) by the amount of food, as percent (decimal of) body weight consumed. A risk quotient is then determined by dividing the EEC by the derived LC_{50} value. Acute RQs are calculated for three separate weight classes of mammals (15, 35, and 1000 g), each presumed to consume four different kinds of food (grass, forage, insects, and seeds). Chronic mammalian RQs are calculated using the most sensitive NOAEC from the 2-generation rat study and the residue concentration expected on food items from Hoerger and Kenaga (1972) as modified by Fletcher *et al.* (1994).

According to proposed labeling banded, applications of sprays to cotton do not make adjustments to the application rate and the resulting treatment concentrates the per acre application rate into a narrow band. Banded applications are commonly adjusted to concentrate the treatment on the plant rather than the surrounding soil between the rows. Therefore, the total per acre application rate can be adjusted (reduced) in proportion to the ratio of the treated to untreated bands. Birds, at least in theory, could be exposed to the higher concentration of toxicant by foraging or wandering into the treated band. EFED evaluated the banded risk to cotton by comparing the RQs from unadjusted band rates to those using the adjusted band rates to illustrate the increased risk. EFED assumed a 6-inch band and 30-inch row space as a typical banded application. The RQs indicate that levels of concern are not exceeded for either the adjusted or unadjusted rates with the exception of the endangered species LOC for 15 g birds when rates have not been adjusted.

The proposed label for use on cotton allows unincorporated banded treatments. Exposure to birds increases for banded applications since birds may forage within and between the treated bands unless the application rates are adjusted. Many labels require the formulators to reduce the application rate according to the following formula.

$$\frac{\textit{band width in inches}}{\textit{row width in inches}} \quad X \quad \textit{Broadcast rate per acre} \quad = \quad \textit{Rate per banded acre}$$

Since the registrant has opted not to adjust the banded application rate per label instructions, EFED will assume a 6-inch band and 30-inch row space as a typical banded application and the following formulas were used to calculate LD_{50} s per square foot.

$$\text{mg ai per ft}^2 = \text{App. Rate lbs ai/Acre} \times 453{,}590 \text{ mg/lbs} \times \text{Acre}/43{,}560 \text{ ft}^2 \times \text{\%unincorporated} \times \text{untreated row space (ft)/Bandwidth (ft)}$$

$$RQ = \frac{\text{mg ai}}{\text{ft}^2} \times \frac{1}{\text{Weight of Animal (g)}} \times \frac{1000 \text{ g}}{\text{kg}} \times \frac{\text{kg}}{\text{LD50 mg}}$$

Risk Quotients

The methodology for calculating RQs is presented in Appendix D. Resulting RQs for the parent toxicity values are presented in detail in Appendix E.

APPENDIX A: Detailed Drinking Water Assessment Memo

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

February 11,2004

MEMORANDUM

SUBJECT: Novaluron Estimated Drinking Water Concentration for Use in the Human Health Drinking Water Risk Assessment.
PC Code: 124002
DP Barcode: D285477 and D285479

FROM: Iwona L. Maher, Chemist
James Hetrick, Ph.D., Senior Scientist
Sid Abel, Branch Chief
Pat Jennings, Risk Assessment Process Leader
Environmental Risk Branch 1
Environmental Fate and Effects Division (7507C)

TO: Kathleen Martin, Chemist
Health Effects Division (7509C)

Tier II PRZM/EXAMS modeling was performed to estimate drinking water concentrations for the human health dietary risk assessment. The crops scenarios were selected to provide high-end drinking water concentrations for each crop and represent the geographic locations where the specific crops are grown in large quantities. The scenarios that were modeled are Pennsylvania, North Carolina and Oregon apples (airblast application), Mississippi cotton (ground and aerial application), and potato in Maine (ground and aerial application). The most conservative estimates were obtained for airblast applications of novaluron to PA apples at the maximum annual application rate of 0.96 lb a.i./acre, applied three times at 0.32 lb a.i./acre with an interval between applications of ten days. The predicted 1 in 10 year annual peak concentrations of novaluron in drinking water from surface water for PA apples of 11.4 µg/L exceeds the solubility of the compound (3 µg/L) , which is expected to be an upper bound environmental concentration. The estimated 1 in 10 year annual mean concentration of novaluron in drinking water is 1.8

μg/L. The 30-year annual mean concentration is 1.2 μg/L. Both peak and annual average concentrations for all other scenarios were lower. Table 1 lists estimated drinking water concentrations from surface water sources for all modeled scenarios.

Novaluron is an insect growth regulator that must be ingested by insect larvae to be fully effective. The pesticide is registered for insect pest control on ornamentals grown in greenhouses and nurseries. The registrant submitted a petition for Novaluron first food use on pome fruits (apples and pears), cotton, and potato. Novaluron, the active ingredient in Rimon, is a benzoylphenyl urea compound whose mode of action results from the inhibition of chitin biosynthesis. RimOn is applied at a maximum rate of 0.09 lb ai/A by either ground or aerial applications up to 3 times per year (0.27 lb ai/yr.) on cotton, at a maximum rate of 0.078 lb ai/A by ground or aerial application up to 3 times per year (0.23 lb ai/) on potato, and at a rate of 0.32 lb ai/A by airblast up to 3 times per year (0.96 lb ai/yr.) on large orchard trees.

A complete set of fate and transport data were submitted for novaluron. Fate data submitted for the novaluron degradate chlorophenyl urea (275-352I) was limited to the adsorption/desorption study. No data were submitted for chloroaniline degradate. Based on laboratory and field studies, novaluron appears to be immobile and ranges from moderately persistent to persistent in the field. It biodegrades in soil under aerobic conditions with half-lives of 7 to14.5 days, strongly adsorbs to soil and sediment (simple K_d values ranged from 95 to 247), and is stable to hydrolysis and photodegradation. Due to its high sorptive properties (Koc = 6,680-11,813) on soil the chemical has low potential for leaching into ground water. In the field, novaluron appears to degrade with half-lives ranging from 20 to 178 days. The laboratory and field data suggest that novaluron may be more persistent in colder climates. At 50 °C and pH 9 novaluron hydrolyzes very rapidly with a half-life of 1.2 days. In aerobic soils it degrades slower at 10 °C (i.e., half-life 31.9 days) than at 20 °C (i.e., half-lives from 7 to 14.5 days). Novaluron has the potential to reach surface water through runoff weeks to months following application, and through spray drift during application.

The HED MARC concluded that parent, chlorophenyl urea (1 -[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy) phenyl] urea) (275-352I), and chloroaniline (3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline) are residues of potential concern to be included in the drinking water assessment. Chlorophenyl urea (275-352I) is a major degradate of novaluron formed in aerobic soil metabolism and aquatic anaerobic metabolism. The degradate appears to be mobile (Kds = 16.7 - 61.5), moderately persistent in soil (decline curve estimated $t_{1/2}$ = 46.5 and 45.6 days; GLN 162-1), and moderately persistent in aquatic environment (decline curve estimated $t_{1/2}$ = 26.6 days; GLN 162-4). It has potential to reach surface water through runoff and has low potential to reach ground water resources. The cloroaniline degradate formed in aerobic soil metabolism. Although formation of chloroaniline in soil didn't exceed 10% of the applied dose (i.e., the maximum concentration was 8.5% at 120 days posttreatemnt). the major degradate chlorophenyl urea (275-352I) is expected to further degrade in the environment to form chloroaniline.

Table 1. Novaluron estimated drinking water concentrations for surface water sources.

Scenario	Application Type	Estimated Drinking Water Concentrations from Surface Water Sources (ppb)		
		1 in 10 year annual peak	1 in 10 year annual mean	36 year annual mean
PA apples (PCA = 0.87)	airblast	11.4*	1.8	1.2
NC apples (PCA = 0.87)	airblast	4.24*	0.60	0.38
OR apples (PCA = 0.87)	airblast	1.6	0.38	0.31
MS cotton (PCA = 0.20)	ground aerial	0.70 0.78	0.07 0.08	0.04 0.05
ME potato (PCA = 0.87)	ground aerial	2.15 2.43	0.38 0.45	0.24 0.32

*These values exceed the measured water solubility of novaluron of 3 μg/L (3 ppb).

Additionally, for novaluron degradates, 1-[3-Chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]urea (275-352I) and 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline (275-309I) a Tier I drinking water assessment was performed. An estimated peak drinking water concentration of 275-352I from surface water sources is 4.6 μg/L and 11.4 μg/L for 275-309I based on novaluron's maximum application rate of 0.32 lb ai/acre applied 3 times a season (0.96 lbs ai/year; apples). An estimated annual average concentration of chlorophenyl urea (275-352I) is 0.86 μg/L and for the chloroaniline is 2.6 μg/L from the same novaluron application rate. Table 2 lists estimated drinking water concentrations for both degradates for all novaluron proposed maximum uses. For modeling assumptions and conversion from the parent to the degradate, refer to the Surface Water Assessment section.

Table 2. Degradates' estimated drinking water concentrations for surface water sources based on Tier I modeling.

Novaluron Metabolite	Crop	Application Rate	Estimated Drinking Water Concentrations from Surface Water Sources (ppb)	
			Peak	Annual Average
chlorophenyl urea	apples:	3 X 0.32 lb a.i./acre	4.56	0.86
	cotton	3 X 0.09 lb a.i./acre	0.30	0.057
	potato	3 X 0.078 lb a.i./acre	1.12	0.21
chloroaniline	apples	3 X 0.32 lb a.i./acre	11.4	2.61
	cotton	3 X 0.09 lb a.i./acre	0.75	0.17
	potato	3 X 0.078 lb a.i./acre	2.80	0.64

SCI-GROW modeling predicted a ground water concentration for novaluron at the annual application rate of 0.96 lb a.i./acre (i.e., three applications of 0.32 lb a.i./acre) of 5.5×10^{-3} μg/L in drinking water from shallow ground water sources. The predicted ground water concentration is 4.5×10^{-3} µg/L for chlorophenyl urea and 9.0×10^{-3} µg/L for chloroaniline from novaluron's maximum application rate (0.96 lb a.i./acre). Both concentrations were estimated with the same assumption used for surface water modeling. These concentrations may be considered as both the peak and annual average upper bound exposures.

INTRODUCTION

Mode of Action

Novaluron is a benzoylphenyl urea insect growth regulating insecticide. Its Larvacidal action results from the inhibition of chitin biosynthesis and interference in the cuticle formation in target pests.

Proposed uses

For food use the registrant proposed two novaluron formulations: 7.5% water dispersible granule (RimOn 7.5WDG) insect growth regulator for control of insect pests on apples and pears, and 10% emulsifiable concentrate (RimOn 10EC) insect growth regulator for use on cotton and potato. The insecticide should be applied to foliage by conventional ground or airblast sprayer. According to the proposed label no more than 0.96 lbs a.i. (RimOn 7.5WDG) may be applied per acre per year, with the maximum rate per application of 0.32 lbs a.i., a minimum intervals of 10 to 14 days between applications, and up to 3 applications per year. No application should be made within 14 days of fruit harvest. RimOn 10EC should be applied via conventional ground or aerial sprayer to cotton and potatoes, or when cotton plants are small, via band application. On cotton, the maximum proposed application rate is 0.27 lb a.i. (RimOn 10EC) per acre per year, with the maximum rate per application of 0.09 lbs a.i., a minimum intervals of 7 to 14 days between applications, and up to 3 applications per year. On potatoes the maximum proposed application rate is 0.23 lb a.i. (RimOn 10EC) per acre per year, a maximum rate per application of 0.078 lbs a.i., a minimum intervals of 10 to 14 days between applications, and up to 3 applications per year. No application should be made within 30 days of harvest (cotton and potatoes).

Table 3. Pesticide Name, Identification Number, Structure, and its Physical/Chemical Properties

Common Name:	Novaluron	
PC Code:	124002	
IUPAC Name:	1-[3-Chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]-3-(2,6-difluorobenzoyl)urea	
CAS Name:	N-[[[3-Chloro-4-[1,1,2-trifluoro-2-(trifluoromethoxy)ethoxy]phenyl]-amino]carbonyl]-2,6-difluorobenzamide	
CAS Number	116714-46-6	
Molecular Formula:	$C_{17}H_9ClF_8N_2O_4$	
Molecular Weight (g/mole):	492.7	
Water Solubility:	3 ug/L at 25 °C	(MRID 45638203)
Vapor Pressure:	1.2×10^{-7} mm Hg	
Henry's Law Constant:	2.0 Pa m^3 Mol^{-1}	
log K_{ow}:	4.3	(MRID 45638405)

Structure:

ENVIRONMENTAL FATE SUMMARY

Environmental fate data indicate that novaluron is immobile and moderately persistent to persistent in the field. Laboratory studies suggest that novaluron's major route of disappearance is microbially-mediated degradation. The chemical tends to strongly adsorb to soil and sediment, and it is stable to abiotic processes. Novaluron has a very low potential to reach ground water. During surface runoff conditions, novaluron may reach water bodies as bound to soil particles and will likely partition into sediments once in surface water. Additionally, contribution to surface water contamination may occur from spray drift.

At 20 °C, in soil under aerobic conditions novaluron metabolizes to form chlorophenyl urea (275-352I) with half-lives ranging from 7 to 14.5 days (20 °C, MRIDs: 44961009 and 44961010) and chloroaniline. At lower temperatures (i.e.,10 °C), novaluron degrades slower (i.e., half-life of 31.9 days (MRID 44961009)) than at 20 °C. In aquatic environments under stratified redox conditions (aerobic conditions in water and anaerobic conditions in soil) the chemical metabolizes with total system half-lives of 9.7 and 19.7 days (MRID 45638206). In laboratory studies it rapidly dissipates from the water column with a half-life of 1.2 days under aerobic conditions and less than 3 days under anaerobic condition. Under anaerobic conditions in water-soil systems it biodegrades slower with half-life a total system half-lives of 49 and 51 days (MRIDs: 45638205 and 45789203). A proposed transformation pathway indicates that in aquatic environments novaluron forms 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl urea (275-352I) and 2,6-difluorobenzoic acid (275-158I, DFBA) through amide hydrolysis. Further hydrolysis of 275-352I yields 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline (275-309I) and hydrolysis of 275-158I yields 2,6-difluorobenzamide (275-157I) (MRID 5638206).

Novaluron appears to be stable to hydrolysis at pH 5, 7, and 9 (pH 9 $t_{1/2}$ (25 °C) = 101 days; MRID 44961008) and stable to both soil and aqueous photolysis (soil photolysis $t_{1/2}$ = 257 days, MRID 45638204; aqueous photolysis $t_{1/2}$ = 187 days, MRID 45638203). At 50 °C at pH 9, however, novaluron appears to hydrolyze rapidly with a half-life of 1.2 days. Novaluron tends to adsorb strongly to soil and sediment. The mean simple K_d values ranged from 95 to 247 ml/g, and K_{oc} values from 6,650 to 11,813 (MRID 44961012). There was no linear relationship between the soil organic carbon content and the K_d values for different soils thus the K_{oc} model may not be appropriate. Because novaluron was tested only at one concentration the Freundlich adsorption/desorption coefficients could not be calculated.

The high sorptive properties of novaluron indicate a low potential for leaching to ground water. In the field dissipation study conducted in North America, sites located in CA, LA, NY, WA, Nova Scotia, and Ontario, novaluron residues were not detected above 0.0851 ppm (Nova Scotia) in the 15-30 cm soil depth and above 0.0606 ppm (Ontario) in the 30-45 cm soil depths (MRID 45789204). In all sites, total water inputs (rainfall plus irrigation) were greater than the 10-year average rainfall except for the Nova Scotia site. Novaluron (RimOn 10EC) was not detected above the LOQ (10 ppb) at any sampling interval or in any replicate sample in the 10-20 cm soil depth when applied to bare soil in Spain and Germany (GLN 164-1; MRID 45638403). In these foreign studies pan evaporation data were not reported to assess whether sufficient moisture was present in the soil to facilitate leaching of the test substance. Irrigation was not applied to any of the test plots during the study trials and monthly rainfall data indicated that in the first 3 to 7 months rainfall was below historical average.

In the domestic terrestrial field dissipation studies novaluron (RimOn 10EC and RimOn 6.7WDG) dissipated with half-lives ranging from 20 to 178 days (i.e., in CA with a half-life of 20 days, in WA with a half-life of 61 days, in Nova Scotia with a 89 days, and in NY with a half-life of 178 days (valid $t_{1/2}$ could not be determined for the LA and Ontario sites)). There is, however, a great deal of uncertainty associated with the half-lives calculated at the NY and Nova Scotia sites due to high data variability, both between replicates and over time. In the field dissipation studies conducted in Spain and Germany, novaluron (RimOn 10EC) dissipated with half-lives ranging from 52 to 178 days (MRID 45638403). In five out of six sites in the North American field studies chlorophenyl (275-352I) urea was detected as a major transformation product (MRID 45789204).

In a microcosm study, novaluron exhibited water column DT9O values ranging from 12 to 20 days for three different test concentrations (i.e., 5, 15, and 50 g a.i./ha treatment level; MRID 45785801). Only low concentrations of novaluron were detected in sediment, demonstrating potential for microbial degradation. This was confirmed by the presence of the main degradate, chlorophenyl urea (275-352I), in the water column of three out of five tested concentration and in soil of the highest tested concentration. Chlorophenyl urea (275-352I) was the only degradate analyzed in water and sediment.

Novaluron appears to accumulate in edible and nonedible fish tissues. In a standard bioconcentration study using the bluegill sunfish, the highest mean bioconcentration factor (BCF) in whole fish was 14,431 x. The half-life for clearance of residues in the bluegill was 3.9 to 7.3 days for whole fish (MRID 45638215).

The major novaluron degradate, 1-[3-chloro-4-(1,1,2-trifluoro-2-trifluorometh oxyethoxy) phenyl]urea (275-352I), was formed in aerobic soil metabolism at a maximum rate of 26.6% of the applied parent at 7 days posttreatment (MRID 44961009). Based on the McCall et al., 1980 classification system the degradate appears to have low to slight mobility in soil (K_{oc} values range from 1950 to 2563 L/kg; 163-1; MRID 45638201). The Freundlich isotherm, however, may not adequately represent adsorption of the compound across all concentrations (the 1/n values were not within the range of 0.9 to 1.1). Based on a laboratory study, novaluron degradates appear to have a very low potential for leaching into ground water. Chlorophenyl urea (275-352I) has the potential to reach surface water through runoff. Its aerobic soil metabolism half-lives estimated from the formation and decline curves (MRID 44961009) are 46.5 and 45.9 days. The degradate may be moderately persistent in the aquatic environment. The half-life was determined from the first-order degradation rate from the maximum concentration in the aerobic aquatic metabolism study (MRID 4538206). The aerobic aquatic metabolism half-life is 26.6 days in a Houghton Meadow water-loamy sand sediment.

Another novaluron degradate of potential concern is 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline (chloroaniline, 275-309I) was formed in the aerobic soil metabolism study at a maximum rate of 8.5% of the applied at 120 days posttreatment, the last sampling interval (MRID 44961009). Additionally, it is expected that chloroaniline is formed from the further degradation of the major degradate chlorophenyl urea (275-352I) (MRIDs: 45638205 and 45789203). In the anaerobic aquatic metabolism study, at the last sampling interval, i.e. 363 days posttreatment, the maximum of 32% of the applied was formed in the soil and 49.8% in the total system, this includes soil and volatilized chloroaniline. This degradate has the potential to be volatile (i.e., its estimated vapor pressure exceeds 10^{-4} mmHg), more mobile (K_{oc} (an estimated value) = 5899) and more persistent than the parent. Degradation rates for chloroaniline could not be calculated due to the lack of formation and decline data.

DRINKING WATER ASSESSMENT

Fate and transport data submitted for novaluron were sufficient to characterize drinking water exposures. Fate data submitted for the novaluron degradate chlorophenyl urea (275-352I) was limited to the adsorption/desorption study. For modeling purpose, chlorophenyl urea (275-352I) aerobic soil mentalism and aerobic aquatic metabolism rates were estimated based on the formation and decline curves from the laboratory studies submitted for the parent (MRIDs: 44961009 and 45638206). No data were submitted for the chloroaniline degradate. Its physico-chemical properties were estimated using structure activity relationships (SAR) (Howard and Meylan, 2001).

Monitoring data for novaluron, chlorophenyl urea (275-352I) and chloroaniline in surface water and ground water were not found. Novaluron is not included in the USGS National Water-Quality Assessment (NAWQA) Program, the Pesticides in Ground Water Database (USEPA, 1992), and it was not an analyte in the National Pesticide Survey (USEPA, 1990). Concentrations of novaluron and its degradates, chlorophenyl urea (275-352I) and chloroaniline in surface water and ground water were estimated using modeling. The drinking water assessment was based on the maximum annual application rates on apples, cotton, and potatoes as specified on the labels. These uses are the only food uses registered or proposed to date.

Surface Water Assessment

For the drinking water assessment, a Tier II PRZM-EXAMS (PRZM 3.12 and EXAMS 2.975) modeling simulation was performed using the index reservoir (IR) scenario and the percent crop area (PCA) adjustment factor for the use of novaluron on apples in PA, NC and OR to represent to pome fruit group, cotton in MS, and potatoes in ME. The crops scenarios were selected to provide high-end drinking water concentrations for each crop and represent the geographic locations where the specific crops are grown in large quantities. For the GIS maps refer to Attachment 1. These graphics indicate that for several of the scenarios, ME potatoes and MS cotton, major combined and single crop production areas are well represented. In addition, several scenarios, OR, PA and NC apples are in productions areas with a high density of community drinking water systems. There are several areas where single or combined crop productions is greater than those areas selected for modeling. These areas have been determined to be less vulnerable to runoff. The East and West coast apple scenarios simulated three applications of 0.32 lbs ai/acre with a 10-day interval between applications per label. The MS cotton scenario simulated three application of 0.09 lbs ai/acre with a 7-day interval between applications per label. The ME potato scenario simulated three applications of 0.078 lbs ai/acre with 10-day interval between applications per label. A graphical interface shell, PE4V01.pl (dated 8/8/2003), was used to facilitate in input of use-specific information in the PRZM input (inp) and the EXAMS chemical files.

There are some uncertainties associated with the results of several input parameters. The half-life of photodegradation in water half-life was estimated from extremely variable data within and between labeled study concentration data (r^2 ranged from 0.0039 to 0.6516). However, because novaluron has a very long photodegradation half-life, it is not expected to impact the confidence in estimating environmental concentrations. The soil adsorption/desorption coefficient was based on supplemental adsorption/desorption data. Novaluron was tested at a single concentration and the Freundlich adsorption/desorption coefficients (K_{ads} and K_{des}) could not be calculated. Additionally, instead of being measured, the concentrations of novaluron adsorbed to the soil were calculated. Aerobic aquatic metabolism data were only available for water/sediment systems tested under stratified redox potential where water was under aerobic and sediment under anaerobic conditions throughout the test. Moreover, foliar dissipation half-lives were not considered in the modeling. Tables 4 and 5 list the PRZM/EXAMS modeling input parameters.

Table 4. Environmental Fate and Chemistry Input Parameters for Novaluron

Parameters	Input Value and Unit	Source of Info/Reference
Maximum Application Rates [1]	apples = 0.359 kg ai/ha cotton = 0.100 kg ai/ha potato = 0.087 kg ai/ha	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35
Maximum Number of Applications	apples = 3 cotton = 3 potato = 3	Product Labels as above
Minimum Interval Between Applications	apples = 10 days cotton = 7 days potato = 10 days	Product Labels as above
Soil Partition Coefficient (K_d)[2]	133 ml/g	MRID 44961012
Molecular Weight	492.7	Registrant data
Solubility (at 25 °C) x 100	0.3 ppm	Registrant data (MRID 45638203)
Vapor Pressure	1.2×10^{-7} mm Hg	Registrant data
Henry's Constant at 25 °C	1.974×10^{-13} atm•m^3/mol	Registrant data
Aerobic Soil Metabolism $T_{1/2}$[3]	15.6 days	MRIDs: 44961009 and 44961010
Foliar Dissipation $T_{1/2}$	-	was not considered in the modeling
Aqueous Photolysis (pH 5) $T_{1/2}$[4]	187 days	MRID 45638203
Hydrolysis $T_{1/2}$ (pH7)	stable	MRID 44961008
Aerobic Aquatic Metabolism Half-life[5]	30.1 days	MRID 45638206
Anaerobic Aquatic Metabolism Half-life[5]	52.1 days	MRIDs: 45638205 and 45789203

[1] - One planting per year was assumed and the annual rate is assumed to be the seasonal rate

[2] - The lowest non-sand K_d for sandy loam with sand content < 70% was used. Out of four K_f values (133, 247, 184, and 95) the lowest non-sand K_f for sandy loam was used (K_{oc} model was not valid).

[3] - Since n=4: to account for the inherent variability the constant rate of the upper confidence bound on the mean (mean half-life (of 14.5, 13.7, 7, and 11.5) + $(t_{90}\ \sigma)/\sqrt{n}$ (single tail student's t, α=0.1 where n = number of values)) aerobic soil metabolism half-life was used

[4] - individual data points were very variable so the accuracy of the half-life is uncertain

[5] - since n=2 (aerobic $T_{1/2}$: 19.7 and 9.7 days; anaerobic $T_{1/2}$: 50.6 and 49.2 days), the upper confidence bound on the mean aquatic metabolism half-life was used.

Table 5. Additional PRZM-EXAM Input Parameters for Novaluron

Parameters	Input Value and Unit	Source of Info/Reference
First Application Date (day-month)	apples = PA: 25-07 NC: 20-05 OR: 05-08 cotton = MS:20-07 potato = ME:15-06	assumed based on crop profiles and probable target insect infestation
Rainfall Data (Metfile)	apples = PA: W14737.dvf NC: W03812.dvf OR: W24229.dvf cotton = MS: W03940.dvf potato = ME: W14607.dvf	Individual crops' scenarios
Application Fraction	apples airblast = 0.99 cotton & potato aerial = 0.95 cotton & potato ground = 0.99	Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides; Feb. 28, 2002
Spray Drift Fraction	apples airblast = 0.063 cotton & potato aerial = 0.16 cotton & potato ground = 0.064	as above

The highest EECs were obtained for airblast application of novaluron to PA apples at the maximum annual application rate of 0.96 lb a.i./acre, applied three times at 0.32 lb a.i./acre with an interval between applications of ten days. The simulated 1 in 10 year annual peak concentration of novaluron in drinking water was 11.4 μg/L in a PA apples index reservoir scenario adjusted for a default PCA factor of 0.87. The annual peak concentration in drinking water from surface water estimated by PRZM/EXAMS exceeded the water solubility of novaluron of 3 μg/L. The simulated 1 in 10 year annual mean concentration of novaluron in drinking water was 1.8 μg/L and 30 year annual mean concentration was 1.2 μg/L in the same scenario. Table 1 lists estimated drinking water concentrations from surface water sources for all modeled scenarios. The PRZM/EXAMS output files for novaluron are presented in Appendix B.

For the degradate chlorophenyl urea (275-352I) Tier I drinking water analysis was performed. For the surface water modeling the FIRST model was used as if chlorophenyl urea (275-352I) was "ground" applied, i.e. as granular, to the field with no spray drift and no foliar interception as the degradate is formed in the top soil layer from the parent. The FIRST model estimates a peak and an annual average value based on the Index Reservoir scenario. It uses a percent cropped area factor (PCA) to adjust the Estimated Environmental Concentrations (EECs) for the fraction of the watershed which is planted in the modeled crop. A default value of 0.87 was used for apples and potato, and estimated 0.20 for cotton cropped area factor. The degradate scenario was based on the following: (1) assuming 26.6% (MRID 44961009) conversion from parent to chlorophenyl urea (275-352I) and (2) using molecular weight conversion to adjust from parent application rate to chlorophenyl urea (275-352I) application rate. Table 6 lists the modeling input parameters.

Table 6. FIRST Input Parameters for 1-[3-Chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]urea

Parameters	Input Value and Unit	Source of Info/Reference
Maximum Application Rates [1]	apples = 0.061 lb/acre cotton = 0.017 lb/acre potato = 0.015 lb/acre	$rate_{der} = rate_{par} * (MW_{deg}/MW_{par}) * (\text{max. \% form. rate}/100)$
Maximum Number of Applications	apples = 3 cotton = 3 potato = 3	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35
Minimum interval between applications	apples = 10 days cotton = 7 days potato = 10 days	Product Labels as above
Soil Partition Coefficient (K_d)[2]	16.7	MRID 45638201 (GLN 163-1)
Aerobic Soil Metabolism $T_{1/2}$[3]	47.1 days	MRID 44961009
Wetted in	No	Product Label
Depth of incorporation (inches)	0	Product Label
Method of application	granular	assumed; a degradate formed in soil
Solubility in water at 20 °C	33 ppm	MRID 45638201
Aerobic aquatic metabolism half-life[4]	79.8 days	MRID 45638206
Aqueous Photolysis $T_{1/2}$	stable	assumed; data not available

[1] – Application rate of 275-352I is based on the maximum formation rate of 26.6 % from parent novaluron found in the aerobic soil metabolism study (MIRD 44961009) and molecular weigh conversion ($MW_{par} = 492.7$; $MW_{deg} = 352.6$).

[2] - the lowest non-sand K_f (sandy loam) was used. Out of four K_f values (35.1; 16.7; 61.5; and 47.6) the lowest non-sand K_f for sandy loam was used (K_f may not equal K_d).

[3] - 275-352I first order non-linear half-lives were estimated from formation and decline curves using the maximum concentration as the initial concentration; since there were two valid half-lives estimated, i.e. 46.5 and 45.9 days, therefore the upper confidence bound on the mean metabolism half-life was used as the model input value.

[4] - a first order non-linear half-life was calculated from formation and decline curve using the maximum concentration as the initial concentration; since there was only one valid half-life (26.6 days; in Houghton Meadow water-loamy sand sediment) available as a model input value $t_{1/2}$ x3 = 79.8 was used.

An estimated peak drinking water concentration of chlorophenyl urea (275-352I) from surface water sources is 4.6 µg/L from novaluron use on apples at the maximum application rate of 0.32 lb ai/acre applied 3 times a season (0.96 lbs ai/year; RimOn 7.5WDG). An estimated annual average concentration of chlorophenyl urea (275-352I) is 0.86 µg/L from the same use rate.

From novaluron use on cotton at the maximum application rate of 0.09 lb ai/acre applied 3 times a season (0.27 lbs ai/year; RimOn 10EC) the estimated peak drinking water concentration of chlorophenyl urea (275-352I) is 0.30 µg/L. From the same use on cotton an estimated annual average concentration is 0.06 µg/L. An estimated peak concentration of chlorophenyl urea (275-352I) is 1.1 µg/L and an estimated annual average concentration is 0.21 µg/L from novaluron use on potato at the maximum application rate of 0.078 lbs ai/acre applied 3 times a season (0.23 lbs ai/year; RimOn 10EC). The FIRST output files for chlorophenyl urea (275-352I) are presented in Appendix II.

Additionally, Tier I drinking water analysis were performed for chloroaniline. Because non of the laboratory studies submitted for novaluron were conducted long enough to establish the pattern of formation and decline of chloroaniline the maximum formation rate is unknown. Therefore, the degradate scenario was based on the following: (1) assuming 100% conversion from parent to chloroaniline and (2) using molecular weight conversion to adjust from parent application rate to chloroaniline application rate. Table 7 lists the modeling input parameters.

Table 7. FIRST Input Parameters for 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline

Parameters	Input Value and Unit	Source of Info/Reference
Maximum Application Rates [1]	apples = 0.20 lb/acre cotton = 0.057 lb/acre potato = 0.049 lb/acre	$rate_{der} = rate_{par} * (MW_{deg}/MW_{par}) * (max. \% form. rate/100)$
Maximum Number of Applications	apples = 3 cotton = 3 potato = 3	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35
Minimum interval between applications	apples = 10 days cotton = 7 days potato = 10 days	Product Labels as above
Soil Partition Coefficient (K_{oc})	5899	Estimated [2]
Aerobic Soil Metabolism $T_{1/2}$	stable	assumed; data not available
Wetted in	No	Product Label
Depth of incorporation (inches)	0	Product Label
Method of application	granular	assumed; a degradate formed in soil
Solubility in water at 25 °C	10.6 ppm	Estimated [2]
Aerobic aquatic metabolism half-life	stable	assumed; data not available
Hydrolysis $T_{1/2}$ (pH7)	stable	assumed; data not available
Aqueous Photolysis $T_{1/2}$	stable	assumed; data not available

– Application rate of 275-309I is based on 100% formation from parent novaluron and molecular weigh conversion ($MW_{par} = 492.7$; $MW_{deg} = 310.6$).

[2] - Estimated using substructure physical/chemical property computer program (Howard and Meylan, 1995).

The estimated peak and annual average drinking water concentrations for chloroaniline are provided in Table 8.

Table 8. FIRST Estimated Peak and Annual Avg. Drinking Water Concentrations for 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline

Crops and Novaluron Application Information (type, max single application rate, max no of applications, min interval between applications)	Chloroaniline Drinking Water Concentrations (ppb)	
	Peak	Annual Average
Apples (airblast, 0.32 lb/acre, 3x, 10 days)	11.4	2.6
Cotton (ground and aerial, 0.09 lb/acre, 3x, 7 days)	0.75	0.17
Potato (ground and aerial, 0.078 lb/acre, 3x, 10 days)	2.8	0.64

The FIRST output files for chloroaniline are presented in Appendix B.

Assumptions and Uncertainties

Due to a lack of physico-chemical properties and fate data for chloroaniline degradate the Tier I modeling is likely a bounding exposure scenario for drinking water. In addition, the assumed 100% conversion from parent to chloroaniline further increases uncertainty of the estimated drinking water concentrations and is likely to result in higher concentrations.

The modeling for chlorphenyl urea (275-352I) was performed based on its maximum formation in soil in the aerobic soil metabolism study (i.e., 26.6% of the applied parent at 7 days posttreatment; MRID 44961009). Novaluron, however, will potentially form up to 33.2% of chlorophenyl urea (275-352I) in sediment as shown by an anaerobic aquatic metabolism study (MRID 45789203). Therefore, the predicted drinking water concentrations for 275-352I may be underestimated.

A change of date of insect treatment may also change the estimates for novaluron drinking water concentrations. Application dates will vary greatly, depending on time of year, weather conditions, stage of crop growth, and when insect outbreaks occur.

Ground Water Assessment

According to the McCall classification (McCall *et al.*, 1980) novaluron appears to be immobile in soils. It is unlikely that novaluron would reach potable ground water resources. In the field dissipation studies conducted in North America, the residues were detected in the 15-30 cm soil depth at maximum concentrations of 0.0851 ppm (Nova Scotia) and 0.0606 ppm in the 30-45 cm soil depths (Ontario) (MRID 45789204). Total water inputs (i.e., rainfall plus irrigation), in these studies were greater than the 10-year average at all sites with the exception of Nova Scotia where water input was 81.5% of the 10-year average. Novaluron (RimOn 10EC) was not detected above the LOQ (10 ppb) at any sampling interval or in any replicate sample in the 10-20 cm soil depth when applied to bare soil in Spain and Germany (GLN 164-1; MRID 45638403). In these studies, however, rainfall, in general, was below historical average during the first three to seven months following application.

Based on a laboratory aged column leaching study novaluron degradates appear to have a very low potential for leaching into ground water. No radio labeled residues were identified below the treated 0-8 cm soil layer. An adsorption-desorption study indicates that chlorophenyl urea (275-352I) appears to have low to slight mobility in soil. Laboratory data are not available for chloroaniline. The degradate has potential to be more mobile than novaluron. Chlorophenyl urea (275-352I), the only degradate analyzed in the field studies, was detected above the LOQ (0.01 ppm) at all sites but CA. In three out of six sites, LA, WA, and Ontario, the degradate was not detected above the LOQ below the 0-15 cm soil depth. At the NY site, the degradate was detected once at 0.0266 ppm (single replicate) in the 15-30 cm soil depth and at the Nova Scotia site was sporadically detected at ≤0.0186 ppm (single replicate) in the 15-30 cm soil depth, and was not detected below that depth.

The SCI-GROW (SG23.exe, version 2.3, dated July 29, 2003) screening model was used to estimate ground water concentrations. The model estimates the upper bound ground water concentrations of pesticides likely to occur when the pesticide is used at the maximum allowable rate in areas where ground water is particularly vulnerable to contamination. Table 9 lists the input parameters used to model concentrations of novaluron in ground water.

Table 9. SCI-GROW Input Parameters for Novaluron

Parameter	Input Value and Units	Source of Info/Reference
Maximum Application Rate [1]	apples = 0.32 lb ai/acre cotton = 0.09 lb ai/acre potato = 0.078 lb ai/acre	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35 (??)
Max Number of Applications per year	apples = 3 cotton = 3 potato = 3	Product Labels as above
Partition Coefficient Normalized to Organic Carbon Content [2] - K_{oc}	9965 L kg o.c.$^{-1}$	MRID 44961012 (GLN 163-1)
Aerobic Soil Metabolism nonlinear $t_{1/2}$ [3]	12.6 days	MRIDs: 44961009 and 44961010 (GLN 162-1)

[1] - One planting per year was assumed and the annual rate is assumed to be the seasonal rate.

[2] - The median K_{oc} value from four measurements (10271, 6650, 9658, and 11813 L/kg) was used.

[3] - There were four aerobic soil metabolism $t_{1/2}$ values (14.5, 13.7, 7, and 11.5 days) available so the median half-life value was used.

Estimated concentrations of novaluron in drinking water from shallow ground water sources are 5.5×10^{-3} µg/L for applications on apples at 0.32 lbs ai/A (RimOn 7.5WDG) applied 3 times per year, 1.6×10^{-3} µg/L for applications on cotton at 0.09 lbs ai/A (RimOn 10EC) applied 3 times per year, and 1.35×10^{-3} µg/L for applications on potatoes at 0.078 lbs ai/A (RimOn 10EC) applied 3 times per year. These concentrations may be considered as both peak and annual average upper bound concentrations.

The SCI-GROW model was also used to estimate ground water concentrations of chlorophenyl urea (275-352I) and chloroaniline. The modeling assumptions were the same as for surface water modeling of the degradates (see Surface Water Assessment). Table 10 lists the modeling input parameters for chlorophenyl urea (275-352I) and Table 11 for chloroaniline.

Table 10. SCI-GROW Input Parameters for 1-[3-Chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)phenyl]urea

Parameter	Input Value and Units	Source of Info/Reference
Maximum Application Rate [1]	apples = 0.061 lb/acre cotton = 0.017 lb/acre potato = 0.015 lb/acre	$rate_{der} = rate_{par} * (MW_{deg}/MW_{par}) * (max. \% form. rate/100)$
Max Number of Applications per year	apples = 3 cotton = 3 potato = 3	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35 (?)
Partition Coefficient Normalized to Organic Carbon Content [2] - K_{oc}	2297 L kg o.c.$^{-1}$	MRID 45638201 (GLN 163-1)
Aerobic Soil Metabolism nonlinear $t_{1/2}$ [3]	46.2 days	MRID 44961009 (GLN 162-1)

[1] – Application rate of 275-352I is based on the maximum formation rate of 26.6 % from parent novaluron found in the aerobic soil metabolism study (MIRD 44961009) and molecular weigh conversion ($MW_{par} = 492.7$; $MW_{deg} = 352.6$).
[2] - The median K_{oc} value from four measurements (1950, 2088, 2563, and 2505 L/kg) was used.
[3] - 275-352I first order non-linear half-lives were estimated from formation and decline curve using the maximum concentration as the initial concentration; since there were two valid half-lives estimated, i.e. 46.5 and 45.9 days, the average value was used as the model input value.

Table 11. SCI-GROW Input Parameters for 3-chloro-4-(1,1,2-trifluoro-2-trifluoromethoxyethoxy)aniline

Parameter	Input Value and Units	Source of Info/Reference
Maximum Application Rate [1]	apples = 0.20 lb/acre cotton = 0.057 lb/acre potato = 0.049 lb/acre	$rate_{der} = rate_{par} * (MW_{deg}/MW_{par}) *$ (max. % form. rate/100)
Max Number of Applications per year	apples = 3 cotton = 3 potato = 3	Product Labels: RimOn 7.5WDG; EPA Reg. No. 66222-LT RimOn 10EC; EPA Reg. No. 66222-35 RimOn 10EC; EPA Reg. No. 66222-35 (?)
Partition Coefficient Normalized to Organic Carbon Content - K_{oc}	5899 L kg o.c.$^{-1}$	Estimated [2]
Aerobic Soil Metabolism nonlinear $t_{1/2}$ [3]	1000 days	assumed; data not available

[1] – Application rate of 275-309I is based on 100% formation from parent novaluron and molecular weigh conversion (MW_{par} = 492.7; MW_{deg} = 310.6).

[2] - Estimated using substructure physical/chemical property computer program (Howard and Meylan, 1995).

[3] - SCI-GROW was developed using aerobic soil metabolism half-lives from 13-1000 days. Due to the lack of aerobic soil metabolism data the highest value of 1000 days was used.

An estimated concentration of chlorophenyl urea (275-352I) in drinking water from shallow ground water sources is 4.5 x 10^{-3} µg/L from novaluron's maximum application rate (RimOn 7.5WDG use on apples). From the same novaluron maximum application rate, an estimated concentration of chloroaniline in drinking water from shallow ground water sources is 9.0 x 10^{-3} µg/L. The SCI-GROW output files for novaluron and its degradates, chlorophenyl urea (275-352I) and chloroaniline are presented in Appendix B.

Assumptions and Uncertainties

SCI-GROW modeling was conducted using K_{oc} values ranging from 32-180 L/Kg. Extrapolation beyond these values further increases the uncertainty of the ground water EECs. Additionally, Koc values for chloroaniline were estimated from a structural activity model. The K_{oc} input value for novaluron was 9965 L/kg o.c., for chlorophenyl urea 2297 L/kg o.c., and for chloroaniline was 5899 L/kg o.c. Given that the K_{oc} of the parent and its degradates are outside the range of the K_{oc} values used to develop SCI-GROW, there is uncertainty regarding the estimated ground water concentrations. The lack of aerobic soil metabolism data for chloroaniline further increases uncertainty of the estimated drinking water concentrations from ground water sources.

Literature Review

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APPENDIX B: PRZM/EXAMS Input & Output Files for Ecological Assessment

Aquatic Exposure Modeling Output Files (PRZM/EXAMS)

A. Output File - Apples
stored as novalPAp.out
Chemical: novaluron
PRZM environment: PAappleC.txt modified Monday, 24 November 2003 at 13:49:49
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w14737.dvf modified Wedday, 3 July 2002 at 09:06:12
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.3064	0.2659	0.2007	0.1317	0.1025	0.03282
1962	3.119	2.834	2.032	1.369	1.146	0.3951
1963	2.66	2.394	1.751	1.217	1.056	0.5695
1964	0.6478	0.6437	0.6266	0.5888	0.5598	0.3222
1965	1.806	1.601	1.332	0.9257	0.8013	0.323
1966	2.898	2.545	1.704	1.336	1.164	0.5517
1967	1.819	1.633	1.175	0.8721	0.7604	0.5148
1968	0.4562	0.4236	0.4121	0.3872	0.3678	0.2479
1969	3.859	3.396	2.514	1.602	1.313	0.4848
1970	0.908	0.818	0.62	0.5392	0.4944	0.3839
1971	5.967	5.309	3.889	2.643	2.264	0.9056
1972	1.278	1.203	1.174	1.105	1.053	0.6593
1973	2.434	2.164	1.487	0.9882	0.8471	0.4059
1974	5.043	4.472	3.128	2.238	1.936	0.8516
1975	1.049	0.9802	0.956	0.8996	0.8562	0.5691
1976	4.645	4.213	2.87	1.901	1.63	0.6733
1977	1.417	1.262	0.8781	0.7491	0.708	0.4949
1978	4.544	4.126	3.19	2.057	1.703	0.6713
1979	2.893	2.59	1.934	1.391	1.2	0.6954
1980	0.7037	0.6999	0.6829	0.6429	0.6118	0.3303
1981	0.3872	0.3395	0.2444	0.1869	0.1703	0.106
1982	6.291	5.663	3.968	2.481	2.043	0.6999
1983	1.502	1.371	0.9772	0.8031	0.7624	0.5275
1984	0.8526	0.7512	0.6761	0.4679	0.3871	0.2571
1985	2.54	2.226	1.736	1.252	1.235	0.5115
1986	1.256	1.164	0.9072	0.7013	0.6042	0.4466
1987	4.539	4.022	2.735	2.206	1.902	0.7455
1988	2.425	2.203	1.633	1.225	1.128	0.7753
1989	1.178	1.066	0.7933	0.6013	0.5717	0.4451
1990	5.02	4.412	2.978	1.846	1.521	0.625

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	6.291	5.663	3.968	2.643	2.264	0.9056
0.0645161290322581	5.967	5.309	3.889	2.481	2.043	0.8516
0.0967741935483871	5.043	4.472	3.19	2.238	1.936	0.7753
0.129032258064516	5.02	4.412	3.128	2.206	1.902	0.7455
0.161290322580645	4.645	4.213	2.978	2.057	1.703	0.6999
0.193548387096774	4.544	4.126	2.87	1.901	1.63	0.6954
0.225806451612903	4.539	4.022	2.735	1.846	1.521	0.6733
0.258064516129032	3.859	3.396	2.514	1.602	1.313	0.6713
0.290322580645161	3.119	2.834	2.032	1.391	1.235	0.6593

0.32258064516129	2.898	2.59	1.934	1.369	1.2	0.625
0.354838709677419	2.893	2.545	1.751	1.336	1.164	0.5695
0.387096774193548	2.66	2.394	1.736	1.252	1.146	0.5691
0.419354838709677	2.54	2.226	1.704	1.225	1.128	0.5517
0.451612903225806	2.434	2.203	1.633	1.217	1.056	0.5275
0.483870967741936	2.425	2.164	1.487	1.105	1.053	0.5148
0.516129032258065	1.819	1.633	1.332	0.9882	0.8562	0.5115
0.548387096774194	1.806	1.601	1.175	0.9257	0.8471	0.4949
0.580645161290323	1.502	1.371	1.174	0.8996	0.8013	0.4848
0.612903225806452	1.417	1.262	0.9772	0.8721	0.7624	0.4466
0.645161290322581	1.278	1.203	0.956	0.8031	0.7604	0.4451
0.67741935483871	1.256	1.164	0.9072	0.7491	0.708	0.4059
0.709677419354839	1.178	1.066	0.8781	0.7013	0.6118	0.3951
0.741935483870968	1.049	0.9802	0.7933	0.6429	0.6042	0.3839
0.774193548387097	0.908	0.818	0.6829	0.6013	0.5717	0.3303
0.806451612903226	0.8526	0.7512	0.6761	0.5888	0.5598	0.323
0.838709677419355	0.7037	0.6999	0.6266	0.5392	0.4944	0.3222
0.870967741935484	0.6478	0.6437	0.62	0.4679	0.3871	0.2571
0.903225806451613	0.4562	0.4236	0.4121	0.3872	0.3678	0.2479
0.935483870967742	0.3872	0.3395	0.2444	0.1869	0.1703	0.106
0.967741935483871	0.3064	0.2659	0.2007	0.1317	0.1025	0.03282
0.1	5.0407	4.466	3.1838	2.2348	1.9326	0.77232

Average of yearly averages: 0.507397333333333

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:
Output File: novalPAp
Metfile: w14737.dvf
PRZM scenario: PAappleC.txt
EXAMS environment file: pond298.exv
Chemical Name: novaluron

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	492.9	g/mol	
Henry's Law Const.	henry	1.97e-13		atm-m^3/mol
Vapor Pressure	vapr	1.2e-7	torr	
Solubility	sol	0.3	mg/L	
Kd	Kd	133	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp	187	days	Half-life
Aerobic Aquatic Metabolism	kbacw	30.1	days	Halfife
Anaerobic Aquatic Metabolism	kbacs	52.1	days	Halfife
Aerobic Soil Metabolism	asm	15.6	days	Halfife
Hydrolysis:	pH 7	0	days	Half-life
Method:	CAM	2	integer	See PRZM manual
Incorporation Depth:	DEPI	0	cm	
Application Rate:	TAPP	0.359	kg/ha	
Application Efficiency:	APPEFF	0.99	fraction	
Spray Drift	DRFT	0.01	fraction of application rate applied to pond	
Application Date	Date	25-07	dd/mm or dd/mmm or dd-mm or dd-mmm	
Interval 1	interval	10	days	Set to 0 or delete line for single app.
Interval 2	interval	10	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
IPSCND		1		

UPTKF			
Record 18: PLVKRT			
PLDKRT			
FEXTRC	0.5		
Flag for Index Res. Run	IR	Pond	
Flag for runoff calc.	RUNOFF	none	none, monthly or total(average of entire run)

B. Output File - Cotton - aerial application
stored as novalMSap.out
Chemical: novaluron
PRZM environment: MScottonC.txt modified Monday, 24 November 2003 at 13:49:38
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w03940.dvf modified Wedday, 3 July 2002 at 09:05:46
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	1.016	0.9044	0.7883	0.5848	0.4733	0.1517
1962	0.7423	0.6349	0.4047	0.2477	0.1978	0.1021
1963	0.4712	0.4018	0.2906	0.1714	0.1284	0.05209
1964	1.234	1.068	0.8452	0.5596	0.4636	0.158
1965	0.5058	0.4476	0.3154	0.2647	0.238	0.1239
1966	1.156	1.016	0.6847	0.4478	0.3626	0.1438
1967	0.8377	0.7417	0.5459	0.4253	0.3719	0.1623
1968	0.4884	0.4193	0.3081	0.2437	0.1957	0.1077
1969	0.7617	0.6641	0.4274	0.317	0.2596	0.1
1970	0.7315	0.6803	0.5679	0.4349	0.3676	0.1463
1971	0.7983	0.716	0.5929	0.359	0.297	0.1288
1972	0.501	0.4277	0.314	0.1923	0.148	0.06493
1973	0.4857	0.4161	0.3122	0.2777	0.2382	0.0871
1974	0.4754	0.4081	0.3276	0.279	0.2366	0.09842
1975	1.31	1.18	0.9321	0.5973	0.4751	0.173
1976	0.852	0.7363	0.5867	0.4787	0.4116	0.1809
1977	0.8554	0.734	0.5416	0.3318	0.267	0.1351
1978	0.4734	0.4044	0.2936	0.1758	0.1433	0.06853
1979	1.787	1.55	1.058	0.7138	0.595	0.2063
1980	0.4882	0.4167	0.3072	0.1836	0.1562	0.1009
1981	0.4649	0.3987	0.2992	0.1986	0.1602	0.06002
1982	1.606	1.479	1.089	0.686	0.5514	0.1885
1983	0.9009	0.7779	0.5146	0.3291	0.2633	0.1307
1984	0.7332	0.66	0.4738	0.3244	0.2603	0.1054
1985	1.65	1.436	0.9233	0.6195	0.5102	0.1862
1986	0.5811	0.5034	0.4271	0.2682	0.2123	0.1125
1987	0.5618	0.4824	0.3772	0.2411	0.1874	0.07338
1988	0.8289	0.7205	0.4861	0.3452	0.2994	0.1163
1989	0.4807	0.4117	0.3002	0.1935	0.1633	0.08574
1990	0.4703	0.401	0.2898	0.1937	0.1707	0.07082

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	1.787	1.55	1.089	0.7138	0.595	0.2063
0.0645161290322581	1.65	1.479	1.058	0.686	0.5514	0.1885
0.0967741935483871	1.606	1.436	0.9321	0.6195	0.5102	0.1862
0.129032258064516	1.31	1.18	0.9233	0.5973	0.4751	0.1809
0.161290322580645	1.234	1.068	0.8452	0.5848	0.4733	0.173
0.193548387096774	1.156	1.016	0.7883	0.5596	0.4636	0.1623

0.225806451612903	1.016	0.9044	0.6847	0.4787	0.4116	0.158
0.258064516129032	0.9009	0.7779	0.5929	0.4478	0.3719	0.1517
0.290322580645161	0.8554	0.7417	0.5867	0.4349	0.3676	0.1463
0.32258064516129	0.852	0.7363	0.5679	0.4253	0.3626	0.1438
0.354838709677419	0.8377	0.734	0.5459	0.359	0.2994	0.1351
0.387096774193548	0.8289	0.7205	0.5416	0.3452	0.297	0.1307
0.419354838709677	0.7983	0.716	0.5146	0.3318	0.267	0.1288
0.451612903225806	0.7617	0.6803	0.4861	0.3291	0.2633	0.1239
0.483870967741936	0.7423	0.6641	0.4738	0.3244	0.2603	0.1163
0.516129032258065	0.7332	0.66	0.4274	0.317	0.2596	0.1125
0.548387096774194	0.7315	0.6349	0.4271	0.279	0.2382	0.1077
0.580645161290323	0.5811	0.5034	0.4047	0.2777	0.238	0.1054
0.612903225806452	0.5618	0.4824	0.3772	0.2682	0.2366	0.1021
0.645161290322581	0.5058	0.4476	0.3276	0.2647	0.2123	0.1009
0.67741935483871	0.501	0.4277	0.3154	0.2477	0.1978	0.1
0.709677419354839	0.4884	0.4193	0.314	0.2437	0.1957	0.09842
0.741935483870968	0.4882	0.4167	0.3122	0.2411	0.1874	0.0871
0.774193548387097	0.4857	0.4161	0.3081	0.1986	0.1707	0.08574
0.806451612903226	0.4807	0.4117	0.3072	0.1937	0.1633	0.07338
0.838709677419355	0.4754	0.4081	0.3002	0.1935	0.1602	0.07082
0.870967741935484	0.4734	0.4044	0.2992	0.1923	0.1562	0.06853
0.903225806451613	0.4712	0.4018	0.2936	0.1836	0.148	0.06493
0.935483870967742	0.4703	0.401	0.2906	0.1758	0.1433	0.06002
0.967741935483871	0.4649	0.3987	0.2898	0.1714	0.1284	0.05209
0.1	1.5764	1.4104	0.93122	0.61728	0.50669	0.18567

Average of yearly averages: 0.120714333333333

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:
Output File: novalMSap
Metfile: w03940.dvf
PRZM scenario: MScottonC.txt
EXAMS environment file: pond298.exv
Chemical Name: novaluron

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	492.9	g/mol	
Henry's Law Const.	henry	1.97e-13		atm-m^3/mol
Vapor Pressure	vapr	1.2e-7	torr	
Solubility	sol	0.3	mg/L	
Kd	Kd	133	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp	187	days	Half-life
Aerobic Aquatic Metabolism	kbacw	30.1	days	Halfife
Anaerobic Aquatic Metabolism	kbacs	52.1	days	Halfife
Aerobic Soil Metabolism	asm	15.6	days	Halfife
Hydrolysis:	pH 7	0	days	Half-life
Method:	CAM	2	integer	See PRZM manual
Incorporation Depth:	DEPI	0	cm	
Application Rate:	TAPP	0.10	kg/ha	
Application Efficiency:	APPEFF	0.95	fraction	
Spray Drift	DRFT	0.05	fraction of application rate applied to pond	
Application Date	Date	20-07	dd/mm or dd/mmm or dd-mm or dd-mmm	
Interval 1	interval	7	days	Set to 0 or delete line for single app.

Interval 2	interval	7	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
IPSCND		1		
UPTKF				
Record 18:	PLVKRT			
PLDKRT				
FEXTRC		0.5		
Flag for Index Res. Run	IR	Pond		
Flag for runoff calc.	RUNOFF		none	none, monthly or total(average of entire run)

C. Output File - Cotton - ground applicvation

stored as novalMSpp.out
Chemical: novaluron
PRZM environment: MScottonC.txt modified Monday, 24 November 2003 at 13:49:38
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w03940.dvf modified Wedday, 3 July 2002 at 09:05:46
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.778	0.6911	0.58	0.4677	0.3857	0.1259
1962	0.3849	0.3313	0.2032	0.1249	0.103	0.0702
1963	0.09645	0.0825	0.06024	0.0361	0.02722	0.01816
1964	1.001	0.8729	0.7301	0.4727	0.396	0.1282
1965	0.4729	0.4147	0.2785	0.1739	0.1467	0.09119
1966	0.972	0.8552	0.5533	0.3388	0.2751	0.1101
1967	0.7711	0.6791	0.4955	0.341	0.2869	0.1271
1968	0.2577	0.2308	0.1691	0.1139	0.1066	0.07196
1969	0.6593	0.5717	0.3605	0.2103	0.168	0.06593
1970	0.6346	0.6024	0.4398	0.3415	0.2881	0.1152
1971	0.5374	0.4679	0.3731	0.2408	0.2033	0.0973
1972	0.1268	0.1091	0.0845	0.05866	0.04914	0.03256
1973	0.3527	0.3125	0.2353	0.1754	0.1469	0.05475
1974	0.3086	0.2705	0.2279	0.1682	0.141	0.06465
1975	1.057	0.9773	0.7283	0.487	0.3925	0.1414
1976	0.7361	0.6884	0.551	0.3828	0.335	0.1495
1977	0.5646	0.4876	0.3223	0.2125	0.1745	0.1028
1978	0.1017	0.08747	0.06525	0.05153	0.0483	0.03459
1979	1.465	1.275	0.8944	0.6202	0.5094	0.1763
1980	0.1783	0.1765	0.1696	0.1554	0.1444	0.06908
1981	0.1529	0.1355	0.09417	0.06928	0.06101	0.02628
1982	1.426	1.26	0.9215	0.5769	0.4697	0.1593
1983	0.6561	0.5672	0.3627	0.2122	0.1698	0.09892
1984	0.5763	0.5026	0.3483	0.2059	0.1663	0.07163
1985	1.567	1.361	0.867	0.5283	0.4339	0.1566
1986	0.3227	0.2787	0.2095	0.1369	0.1159	0.08056
1987	0.2673	0.2392	0.1841	0.111	0.08892	0.03967
1988	0.7544	0.6523	0.4354	0.2831	0.2368	0.08446
1989	0.114	0.1027	0.09082	0.08179	0.07526	0.05182
1990	0.2059	0.1817	0.1458	0.09311	0.07774	0.0369

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	1.567	1.361	0.9215	0.6202	0.5094	0.1763
0.0645161290322581	1.465	1.275	0.8944	0.5769	0.4697	0.1593
0.0967741935483871	1.426	1.26	0.867	0.5283	0.4339	0.1566

0.129032258064516	1.057	0.9773	0.7301	0.487	0.396	0.1495
0.161290322580645	1.001	0.8729	0.7283	0.4727	0.3925	0.1414
0.193548387096774	0.972	0.8552	0.58	0.4677	0.3857	0.1282
0.225806451612903	0.778	0.6911	0.5533	0.3828	0.335	0.1271
0.258064516129032	0.7711	0.6884	0.551	0.3415	0.2881	0.1259
0.290322580645161	0.7544	0.6791	0.4955	0.341	0.2869	0.1152
0.32258064516129	0.7361	0.6523	0.4398	0.3388	0.2751	0.1101
0.354838709677419	0.6593	0.6024	0.4354	0.2831	0.2368	0.1028
0.387096774193548	0.6561	0.5717	0.3731	0.2408	0.2033	0.09892
0.419354838709677	0.6346	0.5672	0.3627	0.2125	0.1745	0.0973
0.451612903225806	0.5763	0.5026	0.3605	0.2122	0.1698	0.09119
0.483870967741936	0.5646	0.4876	0.3483	0.2103	0.168	0.08446
0.516129032258065	0.5374	0.4679	0.3223	0.2059	0.1663	0.08056
0.548387096774194	0.4729	0.4147	0.2785	0.1754	0.1469	0.07196
0.580645161290323	0.3849	0.3313	0.2353	0.1739	0.1467	0.07163
0.612903225806452	0.3527	0.3125	0.2279	0.1682	0.1444	0.0702
0.645161290322581	0.3227	0.2787	0.2095	0.1554	0.141	0.06908
0.67741935483871	0.3086	0.2705	0.2032	0.1369	0.1159	0.06593
0.709677419354839	0.2673	0.2392	0.1841	0.1249	0.1066	0.06465
0.741935483870968	0.2577	0.2308	0.1696	0.1139	0.103	0.05475
0.774193548387097	0.2059	0.1817	0.1691	0.111	0.08892	0.05182
0.806451612903226	0.1783	0.1765	0.1458	0.09311	0.07774	0.03967
0.838709677419355	0.1529	0.1355	0.09417	0.08179	0.07526	0.0369
0.870967741935484	0.1268	0.1091	0.09082	0.06928	0.06101	0.03459
0.903225806451613	0.114	0.1027	0.0845	0.05866	0.04914	0.03256
0.935483870967742	0.1017	0.08747	0.06525	0.05153	0.0483	0.02628
0.967741935483871	0.09645	0.0825	0.06024	0.0361	0.02722	0.01816
0.1	1.3891	1.23173	0.85331	0.52417	0.43011	0.15589

Average of yearly averages: 0.0884336666666667

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:
Output File: novalMSpp
Metfile: w03940.dvf
PRZM scenario: MScottonC.txt
EXAMS environment file: pond298.exv
Chemical Name: novaluron

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	492.9	g/mol	
Henry's Law Const.	henry	1.97e-13		atm-m^3/mol
Vapor Pressure	vapr	1.2e-7	torr	
Solubility	sol	0.3	mg/L	
Kd	Kd	133	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp	187	days	Half-life
Aerobic Aquatic Metabolism	kbacw	30.1	days	Halfife
Anaerobic Aquatic Metabolism	kbacs	52.1	days	Halfife
Aerobic Soil Metabolism	asm	15.6	days	Halfife
Hydrolysis:	pH 7	0	days	Half-life
Method:	CAM	2	integer	See PRZM manual
Incorporation Depth:	DEPI	0	cm	
Application Rate:	TAPP	0.10	kg/ha	
Application Efficiency:	APPEFF	0.99	fraction	

Spray Drift	DRFT	0.01	fraction of application rate applied to pond	
Application Date	Date	20-07	dd/mm or dd/mmm or dd-mm or dd-mmm	
Interval 1	interval	7	days	Set to 0 or delete line for single app.
Interval 2	interval	7	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
IPSCND		1		
UPTKF				
Record 18:	PLVKRT			
PLDKRT				
FEXTRC		0.5		
Flag for Index Res. Run		IR	Pond	
Flag for runoff calc.		RUNOFF	none	none, monthly or total(average of entire run)

D. Output File - Potato - aerial application
stored as novalMEap.out
Chemical: novaluron
PRZM environment: MEpotatoC.txt modified Monday, 24 November 2003 at 13:49:36
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w14607.dvf modified Wedday, 3 July 2002 at 09:05:36
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.4244	0.3732	0.2989	0.2385	0.2068	0.0792
1962	1.1	0.9895	0.7865	0.5411	0.4565	0.2076
1963	0.6651	0.6059	0.457	0.3344	0.2984	0.1868
1964	0.9946	0.8819	0.5997	0.3988	0.3387	0.176
1965	0.4413	0.393	0.3145	0.2491	0.2132	0.1287
1966	0.4128	0.3645	0.2888	0.2103	0.1714	0.08818
1967	0.8458	0.7501	0.5119	0.3565	0.3053	0.1398
1968	0.6096	0.5477	0.4407	0.3442	0.3013	0.1615
1969	0.4654	0.4152	0.3405	0.2921	0.2633	0.1485
1970	0.4348	0.3916	0.34	0.2715	0.2303	0.1274
1971	0.4621	0.4119	0.3213	0.2258	0.1856	0.09779
1972	0.6385	0.5654	0.4106	0.2869	0.2526	0.121
1973	1.266	1.151	0.8559	0.5383	0.4469	0.2067
1974	0.482	0.431	0.3551	0.2608	0.2231	0.1439
1975	0.4141	0.3644	0.2949	0.2525	0.2154	0.111
1976	0.8836	0.8156	0.6572	0.5004	0.4286	0.1979
1977	0.5516	0.4951	0.4184	0.3479	0.3152	0.1897
1978	1.27	1.131	0.7876	0.5352	0.4512	0.2225
1979	0.4857	0.4316	0.3614	0.2695	0.2361	0.1553
1980	0.5398	0.4797	0.436	0.3331	0.2854	0.1429
1981	0.6521	0.5811	0.4581	0.3527	0.3157	0.1657
1982	0.6428	0.5784	0.4501	0.3496	0.3138	0.1753
1983	0.9062	0.8124	0.5928	0.4483	0.3849	0.2008
1984	0.9356	0.8427	0.7285	0.5556	0.4652	0.2314
1985	0.5653	0.5116	0.4414	0.3381	0.2903	0.1711
1986	0.4333	0.3849	0.3054	0.2555	0.2343	0.1339
1987	0.5815	0.5173	0.4198	0.3051	0.2573	0.1341
1988	0.4712	0.4166	0.3269	0.2394	0.2081	0.1129
1989	0.4151	0.3664	0.3091	0.2495	0.2268	0.1179
1990	0.6505	0.5803	0.5033	0.4287	0.3661	0.1741

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	1.27	1.151	0.8559	0.5556	0.4652	0.2314
0.0645161290322581	1.266	1.131	0.7876	0.5411	0.4565	0.2225
0.0967741935483871	1.1	0.9895	0.7865	0.5383	0.4512	0.2076
0.129032258064516	0.9946	0.8819	0.7285	0.5352	0.4469	0.2067
0.161290322580645	0.9356	0.8427	0.6572	0.5004	0.4286	0.2008
0.193548387096774	0.9062	0.8156	0.5997	0.4483	0.3849	0.1979
0.225806451612903	0.8836	0.8124	0.5928	0.4287	0.3661	0.1897
0.258064516129032	0.8458	0.7501	0.5119	0.3988	0.3387	0.1868
0.290322580645161	0.6651	0.6059	0.5033	0.3565	0.3157	0.176
0.32258064516129	0.6521	0.5811	0.4581	0.3527	0.3152	0.1753
0.354838709677419	0.6505	0.5803	0.457	0.3496	0.3138	0.1741
0.387096774193548	0.6428	0.5784	0.4501	0.3479	0.3053	0.1711
0.419354838709677	0.6385	0.5654	0.4414	0.3442	0.3013	0.1657
0.451612903225806	0.6096	0.5477	0.4407	0.3381	0.2984	0.1615
0.483870967741936	0.5815	0.5173	0.436	0.3344	0.2903	0.1553
0.516129032258065	0.5653	0.5116	0.4198	0.3331	0.2854	0.1485
0.548387096774194	0.5516	0.4951	0.4184	0.3051	0.2633	0.1439
0.580645161290323	0.5398	0.4797	0.4106	0.2921	0.2573	0.1429
0.612903225806452	0.4857	0.4316	0.3614	0.2869	0.2526	0.1398
0.645161290322581	0.482	0.431	0.3551	0.2715	0.2361	0.1341
0.67741935483871	0.4712	0.4166	0.3405	0.2695	0.2343	0.1339
0.709677419354839	0.4654	0.4152	0.34	0.2608	0.2303	0.1287
0.741935483870968	0.4621	0.4119	0.3269	0.2555	0.2268	0.1274
0.774193548387097	0.4413	0.393	0.3213	0.2525	0.2231	0.121
0.806451612903226	0.4348	0.3916	0.3145	0.2495	0.2154	0.1179
0.838709677419355	0.4333	0.3849	0.3091	0.2491	0.2132	0.1129
0.870967741935484	0.4244	0.3732	0.3054	0.2394	0.2081	0.111
0.903225806451613	0.4151	0.3664	0.2989	0.2385	0.2068	0.09779
0.935483870967742	0.4141	0.3645	0.2949	0.2258	0.1856	0.08818
0.967741935483871	0.4128	0.3644	0.2888	0.2103	0.1714	0.0792
0.1	1.08946	0.97874	0.7807	0.53799	0.45077	0.20751

Average of yearly averages: 0.154985666666667

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:
Output File: novalMEap
Metfile: w14607.dvf
PRZM scenario: MEpotatoC.txt
EXAMS environment file: pond298.exv
Chemical Name: novaluron

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	492.9	g/mol	
Henry's Law Const.	henry	1.97e-13		atm-m^3/mol
Vapor Pressure	vapr	1.2e-7	torr	
Solubility	sol	0.3	mg/L	
Kd	Kd	133	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp	187	days	Half-life
Aerobic Aquatic Metabolism	kbacw	30.1	days	Halfife
Anaerobic Aquatic Metabolism	kbacs	52.1	days	Halfife
Aerobic Soil Metabolism	asm	15.6	days	Halfife
Hydrolysis:	pH 7	0	days	Half-life

Method:	CAM	2	integer	See PRZM manual
Incorporation Depth:	DEPI	0	cm	
Application Rate:	TAPP	0.087	kg/ha	
Application Efficiency:	APPEFF		0.95	fraction
Spray Drift	DRFT	0.05	fraction of application rate applied to pond	
Application Date	Date	15-06	dd/mm or dd/mmm or dd-mm or dd-mmm	
Interval 1	interval	10	days	Set to 0 or delete line for single app.
Interval 2	interval	10	days	Set to 0 or delete line for single app.
Record 17:	FILTRA			
IPSCND		1		
UPTKF				
Record 18:	PLVKRT			
PLDKRT				
FEXTRC		0.5		
Flag for Index Res. Run		IR	Pond	
Flag for runoff calc.		RUNOFF	none	none, monthly or total(average of entire run)

E. Output File - Potato - ground application

stored as novalMEgp.out
Chemical: novaluron
PRZM environment: MEpotatoC.txt modified Monday, 24 November 2003 at 13:49:36
EXAMS environment: pond298.exv modified Thuday, 29 August 2002 at 16:33:30
Metfile: w14607.dvf modified Wedday, 3 July 2002 at 09:05:36
Water segment concentrations (ppb)

Year	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
1961	0.246	0.2203	0.1556	0.1167	0.108	0.04417
1962	0.9589	0.8604	0.6576	0.4549	0.3831	0.1617
1963	0.4176	0.3876	0.2808	0.2126	0.1915	0.138
1964	0.72	0.64	0.4377	0.2867	0.2427	0.1263
1965	0.1689	0.1576	0.1199	0.1018	0.09538	0.07686
1966	0.09688	0.08773	0.0761	0.06352	0.05453	0.03667
1967	0.6796	0.6005	0.405	0.2624	0.2212	0.09124
1968	0.486	0.434	0.3515	0.2458	0.2077	0.1141
1969	0.2862	0.2633	0.2259	0.1674	0.1493	0.09912
1970	0.3001	0.2688	0.191	0.137	0.122	0.07902
1971	0.1442	0.1322	0.1061	0.0787	0.06825	0.04727
1972	0.3284	0.3063	0.2283	0.1644	0.1487	0.06978
1973	1.046	0.9301	0.7016	0.4458	0.3677	0.1607
1974	0.1788	0.1646	0.1475	0.1311	0.1251	0.09523
1975	0.2209	0.2	0.1647	0.1226	0.1063	0.0615
1976	0.7164	0.6557	0.5166	0.3993	0.3424	0.1513
1977	0.3868	0.3526	0.2746	0.2096	0.204	0.1411
1978	1.063	0.9477	0.6629	0.4302	0.364	0.1761
1979	0.2262	0.2057	0.1633	0.1423	0.1358	0.1076
1980	0.4037	0.3653	0.2809	0.21	0.1798	0.09375
1981	0.3653	0.3287	0.2638	0.2274	0.2136	0.1173
1982	0.5385	0.4812	0.3731	0.2632	0.226	0.1268
1983	0.7599	0.6795	0.4953	0.348	0.2974	0.1538
1984	0.7045	0.6396	0.5348	0.4292	0.365	0.1865
1985	0.4141	0.3743	0.2963	0.2108	0.18	0.123
1986	0.237	0.2169	0.1896	0.1447	0.1269	0.08196
1987	0.3075	0.2757	0.2159	0.1704	0.1462	0.08227
1988	0.1528	0.1373	0.1118	0.1017	0.09493	0.06217
1989	0.2571	0.2349	0.1754	0.1327	0.1207	0.0677

1990	0.4984	0.466	0.3584	0.2998	0.2642	0.1275

Sorted results

Prob.	Peak	96 hr	21 Day	60 Day	90 Day	Yearly
0.032258064516129	1.063	0.9477	0.7016	0.4549	0.3831	0.1865
0.0645161290322581	1.046	0.9301	0.6629	0.4458	0.3677	0.1761
0.0967741935483871	0.9589	0.8604	0.6576	0.4302	0.365	0.1617
0.129032258064516	0.7599	0.6795	0.5348	0.4292	0.364	0.1607
0.161290322580645	0.72	0.6557	0.5166	0.3993	0.3424	0.1538
0.193548387096774	0.7164	0.64	0.4953	0.348	0.2974	0.1513
0.225806451612903	0.7045	0.6396	0.4377	0.2998	0.2642	0.1411
0.258064516129032	0.6796	0.6005	0.405	0.2867	0.2427	0.138
0.290322580645161	0.5385	0.4812	0.3731	0.2632	0.226	0.1275
0.32258064516129	0.4984	0.466	0.3584	0.2624	0.2212	0.1268
0.354838709677419	0.486	0.434	0.3515	0.2458	0.2136	0.1263
0.387096774193548	0.4176	0.3876	0.2963	0.2274	0.2077	0.123
0.419354838709677	0.4141	0.3743	0.2809	0.2126	0.204	0.1173
0.451612903225806	0.4037	0.3653	0.2808	0.2108	0.1915	0.1141
0.483870967741936	0.3868	0.3526	0.2746	0.21	0.18	0.1076
0.516129032258065	0.3653	0.3287	0.2638	0.2096	0.1798	0.09912
0.548387096774194	0.3284	0.3063	0.2283	0.1704	0.1493	0.09523
0.580645161290323	0.3075	0.2757	0.2259	0.1674	0.1487	0.09375
0.612903225806452	0.3001	0.2688	0.2159	0.1644	0.1462	0.09124
0.645161290322581	0.2862	0.2633	0.191	0.1447	0.1358	0.08227
0.67741935483871	0.2571	0.2349	0.1896	0.1423	0.1269	0.08196
0.709677419354839	0.246	0.2203	0.1754	0.137	0.1251	0.07902
0.741935483870968	0.237	0.2169	0.1647	0.1327	0.122	0.07686
0.774193548387097	0.2262	0.2057	0.1633	0.1311	0.1207	0.06978
0.806451612903226	0.2209	0.2	0.1556	0.1226	0.108	0.0677
0.838709677419355	0.1788	0.1646	0.1475	0.1167	0.1063	0.06217
0.870967741935484	0.1689	0.1576	0.1199	0.1018	0.09538	0.0615
0.903225806451613	0.1528	0.1373	0.1118	0.1017	0.09493	0.04727
0.935483870967742	0.1442	0.1322	0.1061	0.0787	0.06825	0.04417
0.967741935483871	0.09688	0.08773	0.0761	0.06352	0.05453	0.03667
0.1	0.939	0.84231	0.64532	0.4301	0.3649	0.1616

Average of yearly averages: 0.106683666666667

Inputs generated by pe4.pl - 8-August-2003

Data used for this run:
Output File: novalMEgp
Metfile: w14607.dvf
PRZM scenario: MEpotatoC.txt
EXAMS environment file: pond298.exv
Chemical Name: novaluron

Description	Variable Name	Value	Units	Comments
Molecular weight	mwt	492.9	g/mol	
Henry's Law Const.	henry	1.97e-13		atm-m^3/mol
Vapor Pressure	vapr	1.2e-7	torr	
Solubility	sol	0.3	mg/L	
Kd	Kd	133	mg/L	
Koc	Koc		mg/L	
Photolysis half-life	kdp	187	days	Half-life
Aerobic Aquatic Metabolism	kbacw	30.1	days	Halfife

Anaerobic Aquatic Metabolism		kbacs	52.1	days	Halfife
Aerobic Soil Metabolism	asm	15.6	days	Halfife	
Hydrolysis:	pH 7	0	days	Half-life	
Method:	CAM	2	integer	See PRZM manual	
Incorporation Depth:	DEPI	0	cm		
Application Rate:	TAPP	0.087	kg/ha		
Application Efficiency:	APPEFF		0.99	fraction	
Spray Drift	DRFT	0.01	fraction of application rate applied to pond		
Application Date	Date	15-06	dd/mm or dd/mmm or dd-mm or dd-mmm		
Interval 1	interval	10	days	Set to 0 or delete line for single app.	
Interval 2	interval	10	days	Set to 0 or delete line for single app.	
Record 17:	FILTRA				
	IPSCND	1			
	UPTKF				
Record 18:	PLVKRT				
	PLDKRT				
	FEXTRC	0.5			
Flag for Index Res. Run		IR	Pond		
Flag for runoff calc.		RUNOFF		none	none, monthly or total(average of entire run)

APPENDIX II

GENEEC Output Files for 275-352I

RUN No. 1. For 275-352I from novaluron application on apples

* INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
.061(.159)	3 10	16.7	33.0	GRANUL(.0)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
47.10	2	N/A	.00- .00	26.60	26.60

GENERIC EECs (IN MICROGRAMS/LITER (PPB)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
2.39	2.33	2.00	1.47	1.19

RUN No. 2. For 275-352I from novaluron application on cotton

* INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
.017(.046)	3 7	16.7	33.0	GRANUL(.0)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
47.10	2	N/A	.00- .00	26.60	26.60

GENERIC EECs (IN NANOGRAMS/LITER (PPTr)) Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
693.45	674.86	581.39	425.94	344.70

RUN No. 3. For 275-352I from novaluron application on potato

* INPUT VALUES *

RATE (#/AC) ONE(MULT)	No.APPS & INTERVAL	SOIL Kd	SOLUBIL (PPM)	APPL TYPE (%DRIFT)	NO-SPRAY ZONE(FT)	INCORP (IN)
.015(.039)	3 10	16.7	33.0	GRANUL(.0)	.0	.0

FIELD AND STANDARD POND HALFLIFE VALUES (DAYS)

METABOLIC (FIELD)	DAYS UNTIL RAIN/RUNOFF	HYDROLYSIS (POND)	PHOTOLYSIS (POND-EFF)	METABOLIC (POND)	COMBINED (POND)
47.10	2	N/A	.00- .00	26.60	26.60

GENERIC EECs (IN NANOGRAMS/LITER (PPTr))   Version 2.0 Aug 1, 2001

PEAK GEEC	MAX 4 DAY AVG GEEC	MAX 21 DAY AVG GEEC	MAX 60 DAY AVG GEEC	MAX 90 DAY AVG GEEC
587.59	571.84	492.65	360.92	292.08

APPENDIX C: Ecological Hazard Data

Table 1: Acute Toxicity of Novaluron to Freshwater Fish							
Species	% a.i.	96-hr LC_{50}, µg/L (confid. int.)	NOAEC (µg/L)	Study Properties[a]	Toxicity Classification	MRID, Author, Year	Status
EPA PC Code: 124002 - Novaluron (GR 572 Technical)							
Rainbow trout	94.3	>960	960	M, F-T	highly toxic	454990-04, Douglas, M.T. et.al., 1989.	Supplemental[b]
Bluegill sunfish	94.3	>960	960	M, F-T	highly toxic	454990-05, Douglas, M.T. et.al., 1989.	Supplemental[b]
EPA PC Code: 124002 - Rimon 10 EC (formulated product)							
Rainbow trout	9.2 w/w	62400 (43100 - 90300) [c]	5420	M, F-T	slightly toxic	456383-14, Jenkins, C.A., 1998.	core
EPA PC Code: 124002 - Chlorophenyl urea (275-352 I) (major degradate)							
Rainbow trout	99.3	530	144	M, S	Highly toxic	454990-06, Jenkins,C., 1999.	core

[a] M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.

[b] Despite several deviations from the protocol, the compound was tested above the limits of solubility.

[c] Study measured concentrations of the formulated product. When concentrations are adjusted in terms of the a.i. the LC50 and NOAEC are 5740 (3970 - 8310) and 499 µg ai/L, respectively.

Table 2: Acute Toxicity of Novaluron to Freshwater Invertebrates							
Species	% a.i.	48-hr EC_{50}, µg/L (confid. int.)	NOAEC (µg/L)	Study Properties[a]	Toxicity Classification	MRID, Author, Year	Status
EPA PC Code: 124002 - Rimon 10 EC (formulated product)							
Daphnia magna	9.1 w/w	4.31 (3.34 - 5.77) [c]	1.26[c]	M, S	very highly toxic	456383-13, Jenkins, C.A., 1998.	core
EPA PC Code: 124002 - Chlorophenyl urea (275-352 I) (major degradate)[b]							
Daphnia magna	96.2	1.91	0.69	M, S	practically non-toxic	454990-07, Jenkins, C.A., 1999.	Supplemental[d]

[a] M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.

[b] Data submitted on parent novaluron (MRID # 454768-02) is invalid due to the high variability of the mean measured concentrations and the resulting uncertainty of the actual concentrations that daphnids were exposed to.

[c] Study measured concentrations of the formulated product. When concentrations are adjusted in terms of the ai the LC50 and the NOAEC are 0.4 (0.31 - 0.52) µg ai/L, respectively.

[d] Several deviations from EPA protocols may have impacted the water quality of this study.

Table 3: Acute Toxicity of Novaluron to Estuarine Fish							
Species	**% a.i.**	**96-hr LC_{50} µg/L (confid. int.)**	**NOAEC (µg/L)**	**Study Properties[a]**	**Toxicity Classification**	**MRID, Author, Year**	**Status**
EPA PC Code: 124002 - Novaluron ("Rimon" Technical)							
Sheepshead minnow	99.9	>2.00	>2.00	M, F-T	very highly toxic	456382-10, Machado, M.W., 2002	Supplemental[b]

[a] M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.

[b] Stability measurements not consistent. Can not be determined if test substance degraded, was limited by solubility, or if some other factors were involved.

Table 4: Acute Toxicity of Novaluron to Estuarine/Marine Invertebrates							
Species	**% a.i.**	**96-hr LC_{50} µg/L (confid. int.)**	**NOAEC (µg/L)**	**Study Properties[a]**	**Toxicity Classification**	**MRID, Author, Year**	**Status**
EPA PC Code: 124002 - Novaluron ("Rimon" Technical)							
Mysid shrimp	>97	0.13 (0.11 - 0.16)	0.087	M, F-T	very highly toxic	456382-09.Machado, M.W., 2002	core
Eastern oyster-larvae/embryo	99.9	1.5 (1.2 - 1.8)	0.23	M, F-T	very highly toxic	456382-08,Cafarella, M.A., 2002	core
EPA PC Code: 124002 - Rimon 10 EC (formulated product)							
Mysid shrimp	9.4	1.28 (0.0094 - 5.53)[b]	0.33423[b]	M, S	very highly toxic	460862-03, Albuquerque, R., 2003	Core

[a] M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.
[b] Study measured LC50 and NOAEC concentrations are 0.12 (0.1 - 0.14) µg ai/L.

Table 5: Chronic (Early-life) Toxicity of Novaluron to Fish							
Species	**% a.i.**	**NOAEC (µg/L)**	**LOAEC (µg/L)**	**Study Properties[a]**	**Most sensitive parameter**	**MRID , Author, Year**	**Status**
EPA PC Code: 124002 - Novaluron ("Rimon" Technical)							
Rainbow trout	99.3	6.16	>6.16	M, F-T	Terminal growth & mortality	456382-16, Jenkins, C.A., 1998.	supplemental[b]
EPA PC Code: 124002 - Rimon 10 EC (formulated product)							
Rainbow trout	9.2 w/w	1210[cd]	3370[d]	M, F-T	Mortality (toxic effects)	456384-06, Jenkins, C.A., 2000	supplemental[b]

[a] M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.
[b] Study not performed to US EPA guideline specifications.
[c] 28 day survival LC50 = 7140 µg formulated product/L 95% c.i.: 466 0 - 10870 µg formulated product/L.
[d] Study measured concentrations of the formulated product. When concentrations are adjusted in terms of the ai, the NOAEC and the LOAEC are 111.32 and 310) µg ai/L, respectively.

Table 6: Chronic (Life-cycle) Toxicity of Novaluron to Invertebrates							
Species	**% ai**	**NOAEC (µg/L)**	**LOAEC (µg/L)**	**Study Properties[a]**	**Most sensitive parameter**	**MRID, Author, Year**	**Status**
EPA PC Code: 124002 - Novaluron ("Rimon" Technical)							
Daphnid	>99	0.0299[b]	0.0628	M, S	Parental survival & offspring production	456382-11, Jenkins, C.A., 1998.	Core
Mysid shrimp	99.9	0.026[c]	0.06	M, F-T	Reductions on terminal male body length.	456382-12, Lima, W., 2002	Supplemental[d]

[a] M=mean-measured chemical concentrations, N=nominal chemical concentrations; F-T=flow-through; S=static.
[b] 28 day survival LC50 = 0.0579 mg/L 95% c.i.: 0.0508 - 0.0707 mg/L.
[c] 28 day survival LC50 = 0.1 mg/L 95% c.i.: 0.09 - 0.12 mg/L.
[d] Daily survival and mortality data were not provided. The first day of brood release was not reported, and second generation were not observed daily for at least 4 days for survival, development, and behavior. Since second generation were counted and then discarded, this study is not repairable.

Table 7: Acute Toxicity of Novaluron to Aquatic Plants							
Species	%a.i.	EC_{50}, mg/L (μg ai/L)	NOAEC (μg/L) a.i.	Most sensitive parameter	Initial/mean measured concentrations	MRID, Author, Year	Status
EPA PC Code: 124002 - Novaluron ("Rimon" Technical)							
Vascular Plant							
Duckweed (*Lemna gibba*)							
Nonvascular Plants							
Marine diatom (*Selenastrum capricornutum*)	99.3	> 9680	9680	cell density	mean	456382-21, Jenkins, 1998.	supplemental[a]
Freshwater diatom (*Navicula pelliculosa*)							
Blue-green algae (*Anabaena flos-aquae*)							
Marine diatom (*Skeletonema costatum*)							
EPA PC Code: 124002 - 275-352 I (a metabolite of Rimon)							
Vascular Plant							
Duck weed (*Lemna gibba*)							
Nonvascular Plants							
Marine diatom (*Selenastrum capricornutum*)	96.2	330 (280 - 390)	105	cell density	mean	456382-22, Jenkins, C.A., 1999.	Core
Freshwater diatom (*Navicula pelliculosa*)							
Blue-green algae (*Anabaena flos-aquae*)							
Marine diatom (*Skeletonema costatum*)							
EPA PC Code: 124002 - Rimon 10 EC (formulated product)							
Vascular Plants							
Duck weed (*Lemna gibba*)	9.7	777[b]	777[b]	biomass & no. of fronds	mean	456382-23, Jenkins, C.A., 2001.	Core

Table 7: Acute Toxicity of Novaluron to Aquatic Plants							
Species	%a.i.	EC_{50}, mg/L (µg ai/L)	NOAEC (µg/L) a.i.	Most sensitive parameter	Initial/mean measured concentrations	MRID, Author, Year	Status
Nonvascular plants							
Marine diatom (*Selenastrum capricornutum*)	9.1	39000 (16000 - 95000)[c]	27200[c]	Cell density and biomass	mean	456384-11, Jenkins, C.A., 1998.	Supplemental[a]
Freshwater diatom (*Navicula pelliculosa*)							
Blue-green algae (*Anabaena flos-aquae*)							
Marine diatom (*Skeletonema costatum*)							

[a] Light intensity not at required 4-5 Klux.
[b] Study measured concentrations of the formulated product. When concentrations are adjusted in terms of the ai, the LC50 / NOAEC is 75.4 µg ai/L.
[c] Study measured concentrations of the formulated product. When concentrations are adjusted in terms of the ai, the LC50 / NOAEC is 3549 and 2475 µg ai/L.

Table 8: Acute Toxicity to Novaluron to Birds (oral administration)							
Species	% a.i.	LD_{50}, mg/kg-bw (conf. interval)	NOAEC, mg/kg-bw	Effects	Toxicity Classification (based on a.i.)	MRID, Author, Year	Status
EPA PC Code: 124002 - Novaluron (GR 572 Technical)							
Bobwhite quail	99.3	>2000	2000	No sub-lethal effects or other treatment related effects were observed.	practically non-toxic	454768-01, Rodgers, M., 1998	core
Mallard duck	94.3	> 2000	2000	No treatment related effects observed.	practically non-toxic	454990-01, Hakin, B, et. al. 1989.	supplemental[a]

[a] Could be up-graded to core if additional information is submitted.

Table 9: Acute Toxicity to Novaluron to Birds (dietary administration)							
Species	% a.i.	LC_{50}, mg/kg-diet (conf. interval)	NOAEC, mg/kg-diet	Effects	Toxicity Classification	MRID, Author, Year	Status
EPA PC Code: 124002 - Novaluron (GR 572 Technical)							
Bobwhite quail	94.3	> 5200	2610	No treatment related effects observed	practically non-toxic	454990-02, Hakin, B. et.al., 1989.	core
Mallard duck	94.3	>5310	5310	No mortalities or sub-lethal treatment related effects	practically non-toxic	454990-03, Hakin, B. et.al., 1988.	core

Table 10: Chronic Toxicity of Novaluron to Birds						
Species	% a.i.	NOAEC (mg/kg-diet)	LOAEC (mg/kg-diet)	Effects	MRID #, Author, Year	Status
		a.i.	a.i.			
124002 - Novaluron / Rimon Technical						
Bobwhite quail	99.3	301	1013	Viable & live embryos, # hatchlings,/hen, # 14 day old survivors,/hen, # 14 day old survivors of hatchlings,	456382-18, Rodgers, M.H., 1999.	core
Mallard duck	≥99.3	9.8	30	Viable embryos/pen, viable 14-day embryos of eggs set	456382-19, Rodgers, M.H., 2001.	core

Table 11: Mammalian Acute Oral Toxicity to Novaluron					
Species	% a.i.	LD_{50} (mg/kg-diet)	Toxicity Classification	MRID #, Author, Year	Status[a]
		a.i.			
124002 - Novaluron / Rimon Technical					
laboratory rat *(Rattus norvegicus)*	93.5	>5000	Practically non-toxic	449610-01, Cuthbert et.al, 1986.	Acceptable

[a] Status (acceptability) based on HEDs guidelines.

Table 12: Mammalian Developmental and Chronic Toxicity to Novaluron						
Test Type	% a.i.	NOAEC (mg ai/kg-diet)	LOAEC (mg ai/kg-diet)	Effects	MRID #, Author, Year	Status[a]
124002 - Novaluron / Rimon Technical						
2-generation reproductive (rats)	99.3	1000 ppm (74.2 mg/kg bw/da)	4000 (297.5 mg/kg bw/da)[b]	- Decreased F_1 sperm counts at 4000 ppm - Increased P & F_1 swelling of spleen at all levels. - Hemosiderosis of spleen at 12,000 ppm - Mean litter size of F_1 offspring decreased at 12,000 ppm -F_2 offspring body weight decreases at day 7	456515-05, Blee, 1999.	Acceptable

[a] Status (acceptability) based on HEDs guidelines.
[b] Based on decrease epidermal sperm counts.

Table 13: Acute Contact Toxicity of Novaluron to Non-target Insects					
Species	% a.i.	Toxicity endpoint Contact LD50 (µg/bee)	Toxicity classification	MRID, Author, Year	Status
EPA PC Code: 124002 - Novaluron ("Rimon" Technical)					
Honey bee (*Apis mellifera*)	99.3	>100	Practically non-toxic	456382-20, Gray, A.P., 1998.	Core[a]
EPA PC Code: 124002 - Rimon 10 EC (formulated product)					
Honey bee (*Apis mellifera*)	9.1	>200	Practically non-toxic	456382-20, Gray, A.P., 1998.	Core[b]

[a] Supplemental for Oral LD50 of >100 µg/bee.
[b] Supplemental for Oral LD50 of >200 µg/bee.

Table 14: Acute Toxicity of Novaluron to Earthworm (*Eisenia foetida*)					
Species	**% a.i.**	**LC50 (mg/kg) (Conf. Interval)**	**NOAEC (mg/kg)**	**MRID, Author, Year**	**Status**
EPA PC Code: 124002 - Novaluron ("Rimon Technical)					
Earthworm (*Eiseenia foetide*)	99.3	>1000	≥1000	456382-24, Rodgers, M.H., 1998.	Supplemental[a]
EPA PC Code: 124002 - Novaluron (Chlorophenyl urea (soil degreadate))					
Earthworm (*Eiseenia foetide*)	99.3	447 (407 - 485)	171	456382-25, Rodgers, M.H., 2001.	Supplemental[a]

[a] Performed under OECD guidelines. Not required by EPA.

APPENDIX D: The Risk Quotient Method

The Risk Quotient Method is the means used by EFED to integrate the results of exposure and ecotoxicity data. For this method, RQs (RQs) are calculated by dividing exposure estimates by ecotoxicity values (i.e., RQ = EXPOSURE/TOXICITY), both acute and chronic. These RQs are then compared to OPP's levels of concern (LOCs). These LOCs are criteria used by OPP to indicate potential risk to non-target organisms and the need to consider regulatory action. EFED has defined LOCs for acute risk, potential restricted use classification, and for endangered species.

The criteria indicate that a pesticide used as directed has the potential to cause adverse effects on nontarget organisms. LOCs currently address the following risk presumption categories:

(1) acute - there is a potential for acute risk; regulatory action may be warranted in addition to restricted use classification;

(2) acute restricted use - the potential for acute risk is high, but this may be mitigated through restricted use classification

(3) acute endangered species - the potential for acute risk to endangered species is high, regulatory action may be warranted, and

(4) chronic risk - the potential for chronic risk is high, regulatory action may be warranted.

Currently, EFED does not perform assessments for chronic risk to plants, acute or chronic risks to non-target insects, or chronic risk from granular/bait formulations to mammalian or avian species.

The ecotoxicity test values (i.e., measurement endpoints) used in the acute and chronic RQs are derived from required studies. Examples of ecotoxicity values derived from short-term laboratory studies that assess acute effects are: (1) LC_{50} (fish and birds), (2) LD_{50} (birds and mammals), (3) EC_{50} (aquatic plants and aquatic invertebrates), and (4) EC_{25} (terrestrial plants). Examples of toxicity test effect levels derived from the results of long-term laboratory studies that assess chronic effects are: (1) LOAEL (birds, fish, and aquatic invertebrates), and (2) NOAEL (birds, fish and aquatic invertebrates). The NOAEL is generally used as the ecotoxicity test value in assessing chronic effects.

Risk presumptions, along with the corresponding RQs and LOCs are summarized in Table E1.

Table 1: Risk Presumptions and LOCs		
Risk Presumption	**RQ**	**LOC**
Birds[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOAEC	1
Wild Mammals[1]		
Acute Risk	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.5
Acute Restricted Use	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day (or LD_{50} < 50 mg/kg)	0.2
Acute Endangered Species	EEC/LC_{50} or LD_{50}/sqft or LD_{50}/day	0.1
Chronic Risk	EEC/NOAEC	1
Aquatic Animals[2]		
Acute Risk	EEC/LC_{50} or EC_{50}	0.5
Acute Restricted Use	EEC/LC_{50} or EC_{50}	0.1
Acute Endangered Species	EEC/LC_{50} or EC_{50}	0.05
Chronic Risk	EEC/NOAEC	1
Terrestrial and Semi-Aquatic Plants		
Acute Risk	EEC/EC_{25}	1
Acute Endangered Species	EEC/EC_{05} or NOAEC	1
Aquatic Plants[2]		
Acute Risk	EEC/EC_{50}	1
Acute Endangered Species	EEC/EC_{05} or NOAEC	1

[1] LD_{50}/sqft = (mg/sqft) / (LD_{50} * wt. of animal)
LD_{50}/day = (mg of toxicant consumed/day) / (LD_{50} * wt. of animal)

[2] EEC = (ppm or ppb) in water

APPENDIX E: Detailed Risk Quotients

Table 1: Aquatic Organism Risk Quotient Calculations for Parent Novaluron for Pome fruit, Cotton, and Potatoes.							
Scenario	Acute Toxicity Threshold, LC_{50} or EC_{50} (µg ai/L)	Chronic Toxicity Threshold , NOAEC (µg ai/L)	Peak Water Conc. (µg ai/L)	21-day Average Water Conc. (µg ai/L)	60-day Average Water Conc. (µg ai/L)	Acute RQ[a]	Chronic Species RQ[b]
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)							
Freshwater Fish	>960 (NOAEC value)	6.16	5.04	3.18	2.24	<NOAEC	0.82
Estuarine fish	>2.00 (NOAEC value)	No data	5.04	3.18	2.24	<NOAEC	-
Freshwater Invert.	0.15[c]	0.0299	5.04	3.18	2.24	33.60 ***	168.56 +
Estuarine Invert. (shrimp)	0.13	0.026	5.04	3.18	2.24	38.77 ***	193.85 +
Estuarine Invert. (oyster)	1.5	0.3[d]	5.04	3.18	2.24	3.36 ***	16.80 +
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; ground equipment)							
Freshwater Fish	>960 (NOAEC value)	6.16	1.39	0.85	0.52	<NOAEC	0.23
Estuarine fish	>2.00 (NOAEC value)	No data	1.39	0.85	0.52	<NOAEC	-
Freshwater Invert.	0.15[c]	0.0299	1.39	0.85	0.52	9.27 ***	46.49 +
Estuarine Invert. (shrimp)	0.13	0.026	1.39	0.85	0.52	10.69 ***	53.46 +
Estuarine Invert. (oyster)	1.5	0.3[d]	1.39	0.85	0.52	0.93 ***	4.63 +
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; aerial equipment)							
Freshwater Fish	>960 (NOAEC value)	6.16	1.58	0.93	0.62	<NOAEC	0.26

Table 1: Aquatic Organism Risk Quotient Calculations for Parent Novaluron for Pome fruit, Cotton, and Potatoes.									
Scenario	**Acute Toxicity Threshold, LC_{50} or EC_{50} (µg ai/L)**	**Chronic Toxicity Threshold, NOAEC (µg ai/L)**	**Peak Water Conc. (µg ai/L)**	**21-day Average Water Conc. (µg ai/L)**	**60-day Average Water Conc. (µg ai/L)**	**Acute RQ[a]**		**Chronic Species RQ[b]**	
Estuarine fish	>2.00 (NOAEC value)	No data	1.58	0.93	0.62	<NOAEC		-	
Freshwater Invert.	0.15[c]	0.0299	1.58	0.93	0.62	10.53	***	52.84	+
Estuarine Invert. (shrimp)	0.13	0.026	1.58	0.93	0.62	12.15	***	60.77	+
Estuarine Invert. (oyster)	1.5	0.3[d]	1.58	0.93	0.62	1.05	***	5.27	+
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; aerial equipment)									
Freshwater Fish	>960 (NOAEC value)	6.16	1.09	0.78	0.54	<NOAEC		0.18	
Estuarine fish	>2.00 (NOAEC value)	No data	1.09	0.78	0.54	<NOAEC		-	
Freshwater Invert.	0.15[c]	0.0299	1.09	0.78	0.54	7.27	***	36.45	+
Estuarine Invert. (shrimp)	0.13	0.026	1.09	0.78	0.54	8.38	***	41.92	+
Estuarine Invert. (oyster0	1.5	0.3[d]	1.09	0.78	0.54	0.73	***	3.63	+
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; ground equipment)									
Freshwater Fish	>960 (NOAEC value)	6.16	0.94	0.65	0.43	<NOAEC		0.15	
Estuarine fish	>2.00 (NOAEC value)	No data	0.94	0.65	0.43	<NOAEC		-	
Freshwater Invert.	0.15[c]	0.0299	0.94	0.65	0.43	6.27	***	31.44	+
Estuarine Invert. (shrimp)	0.13	0.026	0.94	0.65	0.43	7.23	***	36.15	+

Table 1: Aquatic Organism Risk Quotient Calculations for Parent Novaluron for Pome fruit, Cotton, and Potatoes.							
Scenario	Acute Toxicity Threshold, LC_{50} or EC_{50} (µg ai/L)	Chronic Toxicity Threshold, NOAEC (µg ai/L)	Peak Water Conc. (µg ai/L)	21-day Average Water Conc. (µg ai/L)	60-day Average Water Conc. (µg ai/L)	Acute RQ[a]	Chronic Species RQ[b]
Estuarine Invert. (oyster)	1.5	0.3[d]	0.94	0.65	0.43	0.63 ***	3.13 +

[a] * indicates an exceedance of Endangered Species Level of Concern (LOC).
** indicates an exceedance of Acute Restricted Use LOC.
*** indicates an exceedance of Acute Risk LOC.

[b] + indicates an exceedance of Chronic LOC.

[c] Estimated on the assumption that acute to chronic ratio for estuarine invertebrates applies to freshwater invertebrates.

[d] Estimated on the assumption that acute to chronic ratio for oyster is the same as shrimp.

Table 2 : Aquatic Organism Risk Quotient Calculations for RimOn 10 EC (Formulated Product of Novaluron) for Pome fruit, Cotton, and Potatoes.				
Scenario	Acute Toxicity Threshold, LC_{50} or EC_{50} (µg product/L)	Peak Water Conc. (µg ai/L)	Acute RQ[a]	
Pome Fruit (3.478 lb product/A; single application air blast equipment 5% drift)				
Freshwater Fish	62400	3.95	0.000063	
Estuarine/Marine Fish	No data	3.95	--	
Freshwater Invert.	4.31	3.95	0.9165	
Estuarine Invert.	0.12	3.95	32.92	***
Pome Fruit (3.478 lb product/A; single application ground equipment 1% drift)				
Freshwater Fish	62400	0.79	0.000013	
Estuarine/Marine Fish	No data	0.79	--	
Freshwater Invert.	4.31	0.79	0.18	**
Estuarine Invert.	0.12	0.79	6.58	***
Cotton (0. 9783 lb product/A/; single application; ground equipment 1% drift)				
Freshwater Fish	62400	0.22	0.000004	
Estuarine/Marine Fish	No data	0.22	--	
Freshwater Invert.	4.31	0.22	0.05	*
Estuarine Invert.	0.12	0.22	1.83	***
Cotton (0.9783 lb product/A/; single application; aerial equipment 5% drift)				
Freshwater Fish	62400	1.11	0.000018	
Estuarine/Marine Fish	No data	1.11	--	
Freshwater Invert.	4.31	1.11	0.26	**
Estuarine Invert.	0.12	1.11	9.25	***
Potato (0.8478 lb product/A; single application; ground equipment 1% drift)				
Freshwater Fish	62400	0.19	0.000003	
Estuarine/Marine Fish	No data	0.19	--	
Freshwater Invert.	4.31	0.19	0.04	
Estuarine Invert.	0.12	0.19	1.58	***
Potato (0.8478 lb product/A; single application; aerial equipment 5% drift)				

Table 2 : Aquatic Organism Risk Quotient Calculations for RimOn 10 EC (Formulated Product of Novaluron) for Pome fruit, Cotton, and Potatoes.				
Scenario	**Acute Toxicity Threshold, LC_{50} or EC_{50} (µg product/L)**	**Peak Water Conc. (µg ai/L)**	**Acute RQ[a]**	
Freshwater Fish	62400	0.96	0.00002	
Estuarine/Marine Fish	No data	0.96	--	
Freshwater Invert.	4.31	0.96	0.22	**
Estuarine Invert.	0.12	0.96	8.00	***

a * indicates an exceedance of Endangered Species Level of Concern (LOC).
** indicates an exceedance of Acute Restricted Use LOC.
*** indicates an exceedance of Acute Risk LOC.

Table 3: Aquatic Organism Risk Quotient Calculations for Chlorophenyl Urea (275 352 I) for Pome fruit, Cotton, and Potatoes.							
Scenario	Acute Toxicity Threshold, LC_{50} or EC_{50} (µg ai/L)	Chronic Toxicity Threshold, NOEC (µmg ai/L)	Peak Water Conc. (µg ai/L)	21-day Average Water Conc. (µg ai/L)	60-day Average Water Conc. (µg ai/L)	Acute RQ[a]	Chronic RQ[b]
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)							
Freshwater Fish	530	No data	2.39	2.00	1.47	0.005	-
Estuarine fish	No data	No data	2.39	2.00	1.47	-	-
Freshwater Invert.	1910	No data	2.39	2.00	1.47	0.001	-
Estuarine Invert.	No data	No data	2.39	2.00	1.47	-	-
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; ground equipment)							
Freshwater Fish	530	No data	0.69	0.58	0.43	0.001	-
Estuarine fish	No data	No data	0.69	0.58	0.43	-	-
Freshwater Invert.	1910	No data	0.69	0.58	0.43	0.000	-
Estuarine Invert.	No data	No data	0.69	0.58	0.43	-	-
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; aerial equipment)							
Freshwater Fish	530	No data	0.59	0.49	0.36	0.001	-
Estuarine fish	No data	No data	0.59	0.49	0.36	-	-
Freshwater Invert.	1910	No data	0.59	0.49	0.36	0.000	-
Estuarine Invert.	No data	No data	0.59	0.49	0.36	-	-

[a] * indicates an exceedance of Endangered Species Level of Concern (LOC).
** indicates an exceedance of Acute Restricted Use LOC.
*** indicates an exceedance of Acute Risk LOC.

[b] + indicates an exceedance of Chronic LOC.

Table 4: Aquatic Plant Risk Quotient Calculations for the Parent Novaluron for Pome Fruit, Cotton, and Potato.						
Scenario	Acute Toxicity Threshold, LC_{50} or EC_{50} (µg ai/L)	Endangered Species Toxicity Threshold, NOAEC (µg ai /L)	Peak Water Concentration (µg ai/L)		Acute RQ[a]	Endangered Species RQ[bc]
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)						
Aquatic Vascular Plant (*Lemna gibba*)	No data	No data	5.04000		--	--
Marine diatom (*Selenastrum capricornutum*)	>9680	9680	5.04000	<	0.0005	0.0005
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; ground equipment)						
Aquatic Vascular Plant (*Lemna gibba*)	No data	No data	1.58		--	--
Marine diatom (*Selenastrum capricornutum*)	>968	9680	1.58	<	0.0016	0.0002
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; aerial equipment)						
Aquatic Vascular Plant (*Lemna gibba*)	No data	No data	0.00109		--	--
Marine diatom (*Selenastrum capricornutum*)	>9680	9680	0.00109	<	0.0000	0.0000

[a] * indicates an exceedence of Acute Risk LOC

[b] ** indicates an exceedence of Endangered Species LOC.

[c] There are currently no endangered nonvascular plant species

Table 5: Aquatic Organism Risk Quotient Calculations for RimOn 10 EC (Formulated Product of Novaluron) for Pome fruit, Cotton, and Potatoes.					
Scenario	**Acute Toxicity Threshold, LC_{50} or EC_{50} (µg product/L)**	**Endangered Species Toxicity Threshold, NOAEC (µg product/L)**	**Peak Water Conc. (µg ai/L)**	**Acute RQ[a]**	**Endangered Species RQ[bc]**
Pome Fruit (3.478 lb product/A; single application air blast equipment 5% drift)					
Aquatic Vascular Plant (*Lemna gibba*)	777	777	3.95	0.005	0.005
Marine diatom (*Selenastrum capricornutum*	39000	27200	3.95	0.000	0.000
Pome Fruit (3.478 lb product/A; single application ground equipment 1% drift)					
Aquatic Vascular Plant (*Lemna gibba*)	777	777	0.79	0.001	0.001
Marine diatom (*Selenastrum capricornutum*	39000	27200	0.79	0.000	0.000
Cotton(0.9783 lb product/A; single application air blast equipment 5% drift)					
Aquatic Vascular Plant (*Lemna gibba*)	777	777	1.11	0.001	0.001
Marine diatom (*Selenastrum capricornutum*	39000	27200	1.11	0.000	0.000
Cotton (0.9783 lb product/A; single application ground equipment 1% drift)					
Aquatic Vascular Plant (*Lemna gibba*)	777	777	0.22	0.000	0.000
Marine diatom (*Selenastrum capricornutum*	39000	27200	0.22	0.000	0.000
Potato (0.8478 lb product/A; single application air blast equipment 5% drift)					
Aquatic Vascular Plant (*Lemna gibba*)	777	777	0.96	0.001	0.001
Marine diatom (*Selenastrum capricornutum*	39000	27200	0.96	0.000	0.000
Cotton (0.8478 lb product/A; single application ground equipment 1% drift)					
Aquatic Vascular Plant (*Lemna gibba*)	777	777	0.19	0.000	0.000

Table 5: Aquatic Organism Risk Quotient Calculations for RimOn 10 EC (Formulated Product of Novaluron) for Pome fruit, Cotton, and Potatoes.					
Scenario	Acute Toxicity Threshold, LC_{50} or EC_{50} (µg product/L)	Endangered Species Toxicity Threshold, NOAEC (µg product/L)	Peak Water Conc. (µg ai/L)	Acute RQ[a]	Endangered Species RQ[b,c]
Marine diatom (*Selenastrum capricornutum*	39000	27200	0.19	0.000	0.000

[a] * indicates an exceedence of Acute Risk LOC

[b] ** indicates an exceedence of Endangered Species LOC.

[c] There are currently no endangered nonvascular plant species

Table 6: Aquatic Plant Risk Quotient Calculations for Chlorophenyl Urea (275 352 I) for Pome Fruit, Cotton, and Potato.					
Scenario	**Acute Toxicity Threshold, LC_{50} or EC_{50} (µg ai/L)**	**Endangered Species Toxicity Threshold, NOAEC (µg ai/L)**	**Peak Water Concentration (µg ai/L)**	**Acute RQ[a]**	**Endangered Species RQ[bc]**
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)					
Aquatic Vascular Plant (*Lemna gibba*)	No data	No data	5.04	-	-
Marine diatom (*Selenastrum capricornutum*)	330	105	5.04	0.01527	0.04800
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; ground equipment)					
Aquatic Vascular Plant (*Lemna gibba*)	No data	No data	1.58	-	-
Marine diatom (*Selenastrum capricornutum*)	330	105	1.58	0.00479	0.01505
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; aerial equipment)					
Aquatic Vascular Plant (*Lemna gibba*)	No data	No data	1.09	-	-
Marine diatom (*Selenastrum capricornutum*)	330	105	1.09	0.00330	0.01038

a * indicates an exceedence of Acute Risk LOC
b ** indicates an exceedence of Endangered Species LOC.
c There are currently no endangered nonvascular plant species

Table 7: Avian Acute and Chronic Risk Quotient Calculations for Pome Fruit, Cotton, and Potatoes - Multiple Applications					
	Acute Toxicity Threshold, LC_{50} (mg ai /kg-diet)	**Chronic Toxicity Threshold, NOEC (mg ai/kg-diet)**	**Predicted Maximum Residue Levels (EEC)(mg ai/kg-diet)**	**Acute RQ [a]**	**Chronic RQ [b]**
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)					
Short grass	>5200	9.8	191.48	<0.04	19.5[+]
Tall grass	>5200	9.8	87.76	<0.02	9.0[+]
Broadleaf forage, small insects	>5200	9.8	107.71	<0.02	11[+]

Table 7: Avian Acute and Chronic Risk Quotient Calculations for Pome Fruit, Cotton, and Potatoes - Multiple Applications					
	Acute Toxicity Threshold, LC_{50} (mg ai /kg-diet)	**Chronic Toxicity Threshold, NOEC (mg ai/kg-diet)**	**Predicted Maximum Residue Levels (EEC)(mg ai/kg-diet)**	**Acute RQ [a]**	**Chronic RQ [b]**
Fruit, pods, seeds, large insects	>5200	9.8	11.97	<0.0023	1.2+
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; ground and aerial equipment)					
Short grass	>5200	9.8	56.77	<0.01	5.8+
Tall grass	>5200	9.8	26.02	<0.005	2.7+
Broadleaf forage, small insects	>5200	9.8	31.94	<0.006	3.3+
Fruit, pods, seeds, large insects	>5200	9.8	3.55	<0.00068	0.36
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and aerial equipment)					
Short grass	>5200	9.8	46.67	<0.01	4.8+
Tall grass	>5200	9.8	21.39	<0.004	2.2+
Broadleaf forage, small insects	>5200	9.8	26.95	<0.005	2.8+
Fruit, pods, seeds, large insects	>5200	9.8	2.92	<0.00056	0.30

[a] * indicates an exceedence of Endangered Species Level of Concern (LOC).
** indicates an exceedence of Acute Restricted Use LOC.
*** indicates an exceedence of Acute Risk LOC.

[b] + indicates an exceedence of Chronic LOC.

Table 8: Avian Acute and Chronic Risk Quotient Calculations for Pome Fruit, Cotton, and Potatoes - Single Applications							
	Acute Toxicity Threshold, LC_{50} (mg ai/kg-diet)	Chronic Toxicity Threshold, NOEC (mg ai/kg-diet)	Predicted Maximum Residue Levels (EEC)(mg ai/kg-diet)	Predicted Mean Residue Levels(EEC)(mg ai/kg-diet)	Acute RQ [a]	Chronic RQ [b] (Max. Residue)	Chronic RQ [b] (Mean Residue)
Pome Fruit (0.32 lb ai/A/App.)							
Short grass	>5200	9.8	76.8	27.2	<0.015	7.8+	2.3+
Tall grass	>5200	9.8	35	11.5	<0.0067	3.6+	1.2+
Broadleaf forage, small insects	>5200	9.8	43.2	14.4	<0.0083	4.4+	1.5+
Fruit, pods, seeds, large insects	>5200	9.8	4.8	2.2	≤0.0009	0.49	0.22
Cotton (0.09 lb ai/A/App)							
Short grass	>5200	9.8	21.6	7.7	<0.0041	2.2+	0.78
Tall grass	>5200	9.8	9.9	3.2	<0.0019	1.0+	0.33
Broadleaf forage, small insects	>5200	9.8	12.5	4.1	<0.0024	1.3+	0.42
Fruit, pods, seeds, large insects	>5200	9.8	1.35	0.6	<0.0001	0.14	0.06
Potato (0.078 lb ai/A/App.)							
Short grass	>5200	9.8	18.72	6.6	<0.0036	1.9+	0.67
Tall grass	>5200	9.8	8.58	2.8	<0.002	0.88	0.29
Broadleaf forage, small insects	>5200	9.8	10.53	3.5	<0.002	1.07+	0.36
Fruit, pods, seeds, large insects	>5200	9.8	1.17	0.6	<0.0001	0.12	0.06

[a] * indicates an exceedence of Endangered Species Level of Concern (LOC).
** indicates an exceedence of Acute Restricted Use LOC.
*** indicates an exceedence of Acute Risk LOC.

[b] + indicates an exceedence of Chronic LOC.

Table 9: Chronic Avian Risk Quotients From Maximum Concentration for Selected Foliar Dissipation Half-Life Values (ppm)								
Pome Fruit								
Foliar Dissipation Half-Life (Days)	**Avian and Mammalian Food Types**							
	Short Grass		**Tall Grass**		**Broadleaf/Forage Plants/Small Insects**		**Fruits, Pods, Seeds, Large Insects**	
	Max. Conc.	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**
1	76.88	**7.8**$^{+}$	35.23	**3.6**$^{+}$	43.24	**4.4**$^{+}$	4.8	0.51
5	100.8	**10.3**$^{+}$	46.2	**4.7**$^{+}$	56.7	**5.8**$^{+}$	6.3	0.64
35	191.48	**19.5**$^{+}$	87.76	**9.0**$^{+}$	107.71	**11.0**$^{+}$	11.97	**1.22**$^{+}$
Cotton								
Foliar Dissipation Half-Life (Days)	**Avian and Mammalian Food Types**							
	Short Grass		**Tall Grass**		**Broadleaf/Forage Plants/Small Insects**		**Fruits, Pods, Seeds, Large Insects**	
	Max. Conc.	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**
1	21.97	**2.2**$^{+}$	9.98	**1.1**$^{+}$	12.25	**1.3**$^{+}$	1.36	0.14
5	32.89	**3.4**$^{+}$	15.07	**1.5**$^{+}$	18.5	**1.9**$^{+}$	2.06	0.21
35	56.77	**5.8**$^{+}$	26.02	**2.7**$^{+}$	31.94	**3.3**$^{+}$	3.55	0.36
Potato								
Foliar Dissipation Half-Life (Days)	**Avian and Mammalian Food Types**							
	Short Grass		**Tall Grass**		**Broadleaf/Forage Plants/Small Insects**		**Fruits, Pods, Seeds, Large Insects**	
	Max. Conc.	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**	**Max. Conc.**	**Risk Quot.**
1	18.74	**1.9**$^{+}$	8.59	0.88	10.54	**1.1**$^{+}$	1.17	0.13
5	24.57	**2.5**$^{+}$	11.26	**1.2**$^{+}$	13.82	**1.4**$^{+}$	1.54	0.16
35	46.67	**1.9**$^{+}$	21.39	**2.2**$^{+}$	26.25	**2.7**$^{+}$	2.92	0.3

+ indicates an exceedence of Chronic LOC.

Table 10: Avian Acute Risk Quotient Calculations for Banded Spray Applications									
Animal Body Weight (g)	Band width (ft.)	Untreated Row Space (ft)	Adjusted Appl. Rate[a]	Unadjusted Appl. Rate (from label)	Mg ai per ft^2 [b]		Acute Toxicity Threshold, LD_{50} (mg/kg)	Acute RQ (LD_{50} per ft^2)[c]	
					Adjusted	Unadjusted		Adjusted	Unadjusted
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; ground and aerial equipment)									
15	0.5	2	0.018	0.09	0.749736	3.74867769	2000	0.03	0.13 *
35	0.5	2	0.018	0.09	0.749736	3.74867769	2000	0.01	0.05
1000	0.5	2	0.018	0.09	0.749736	3.74867769	2000	<0.01	<0.01

[a] *Rate per banded acre* $= \dfrac{\textit{band width in inches}}{\textit{row width in inches}} \times$ *Broadcast rate per acre*

where row width = band width + untreated row space

[b] $\textit{mg ai per ft}^2 = \dfrac{\textit{App. Rate lbs ai}}{\textit{Acre}} \times \dfrac{\textit{453,590 mg}}{\textit{Lbs}} \times \dfrac{\textit{Acre}}{\textit{43,560 ft}^2} \times \textit{\% unincorporated} \times \dfrac{\textit{untreated row space (ft)}}{\textit{Bandwidth (ft)}}$

[c] $RQ = \dfrac{\text{Mg ai}}{\text{ft}^2} \times \dfrac{1}{\text{Weight of Animal (g)}} \times \dfrac{1000\text{ g}}{\text{kg}} \times \dfrac{\text{kg}}{\text{LD50 mg}}$

* indicates an exceedence of Endangered Species Level of Concern (LOC).
** indicates an exceedence of Acute Restricted Use LOC.
*** indicates an exceedence of Acute Risk LOC.

Table 11: Mammalian (Herbivore/Insectivore) Acute Risk Quotient Calculations for Spray Applications							
Animal Body Weight (g)	% Body Weight Consumed	Scenario	Acute Toxicity Threshold, LD_{50} (mg/kg-bw)	Predicted Maximum Residue Levels		Predicted Mean Residue Levels	
				EEC (mg/kg-diet)	Acute RQ [a]	EEC (mg/kg-diet)	Acute RQ [a]
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground a <0.01 nd air blast equipment)							
15	95	Short grass	>5000	191	0.04	68	<0.01
		Broadleaf forage, small insects	>5000	108	0.02	36	<0.01
		Large insects	>5000	12	<0.01	5.6	<0.01
35	66	Short grass	>5000	191	0.03	68	<0.01
		Broadleaf forage, small insects	>5000	108	0.01	36	<0.01
		Large insects	>5000	12	<0.01	5.6	<0.01
1000	15	Short grass	>5000	191	0.01	68	<0.01
		Broadleaf forage, small insects	>5000	108	<0.01	36	<0.01
		Large insects	>5000	12	<0.01	5.6	<0.01
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; aerial and ground equipment)							
15	95	Short grass	>5000	57	0.01	20	<0.01
		Broadleaf forage, small insects	>5000	32	0.01	11	<0.01
		Large insects	>5000	4	<0.01	2	<0.01
35	66	Short grass	>5000	57	0.01	20	<0.01
		Broadleaf forage, small insects	>5000	32	<0.01	11	<0.01
		Large insects	>5000	4	<0.01	2	<0.01
1000	15	Short grass	>5000	57	<0.01	20	<0.01
		Broadleaf forage, small insects	>5000	32	<0.01	11	<0.01
		Large insects	>5000	4	<0.01	2	<0.01
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and aerial equipment)							
15	95	Short grass	>5000	47	0.01	17	<0.01
		Broadleaf forage, small insects	>5000	26	<0.01	9	<0.01

Table 11: Mammalian (Herbivore/Insectivore) Acute Risk Quotient Calculations for Spray Applications							
Animal Body Weight (g)	% Body Weight Consumed	Scenario	Acute Toxicity Threshold, LD_{50} (mg/kg-bw)	Predicted Maximum Residue Levels		Predicted Mean Residue Levels	
				EEC (mg/kg-diet)	Acute RQ [a]	EEC (mg/kg-diet)	Acute RQ [a]
		Large insects	>5000	3	<0.01	1.4	<0.01
		Short grass	>5000	47	0.01	17	<0.01
35	66	Broadleaf forage, small insects	>5000	26	<0.01	9	<0.01
		Large insects	>5000	3	<0.01	1.4	<0.01
		Short grass	>5000	47	<0.01	17	<0.01
1000	15	Broadleaf forage, small insects	>5000	26	<0.01	9	<0.01
		Large insects	>5000	3	<0.01	1.4	<0.01

Table 12: Mammalian (Granivore) Acute Risk Quotient Calculations for Spray Applications							
Animal Body Weight (g)	% Body Weight Consumed	Scenario	Acute Toxicity Threshold, LD_{50} (mg/kg-bw)	Predicted Maximum Residue Levels		Predicted Mean Residue Levels	
				EEC (mg/kg-diet)	Acute RQ [a]	EEC (mg/kg-diet)	Acute RQ [a]
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)							
15	21	Seeds	>5000	12	0.01	5.6	<0.01
35	15	Seeds	>5000	12	<0.01	5.6	<0.01
1000	3	Seeds	>5000	12	<0.01	5.6	<0.01
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; aerial and ground equipment)							
15	21	Seeds	>5000	3.5	<0.01	1.6	<0.01
35	15	Seeds	>5000	3.5	<0.01	1.6	<0.01
1000	3	Seeds	>5000	3.5	<0.01	1.6	<0.01
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and aerial equipment)							
15	21	Seeds	>5000	2.9	<0.01	1.4	<0.01
35	15	Seeds	>5000	2.9	<0.01	1.4	<0.01
1000	3	Seeds	>5000	2.9	<0.01	1.4	<0.01

[a] $RQ = \dfrac{EEC}{LD_{50} / \text{\% Body wt. consumed}}$

* indicates an exceedence of Endangered Species Level of Concern (LOC).
** indicates an exceedence of Acute Restricted Use LOC.
*** indicates an exceedence of Acute Risk LOC.

Table 13 : Mammalian Chronic Risk Quotient Calculations for Spray Applications					
Scenario	Chronic Toxicity Threshold, NOEC (mg/kg-bw/da)	Predicted Maximum Residue Levels		Predicted Mean Residue Levels	
		EEC (mg/kg-diet)	Chronic RQ [a]	EEC (mg/kg-diet)	Chronic RQ [a]
Pome Fruit (0.32 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and air blast equipment)					
Short grass	1000	191	0.19	68	0.36
Tall grass	1000	88	0.09	28.8	0.33
Broadleaf forage, small insects	1000	108	0.11	36	0.33
Large insects, Seeds	1000	12	0.01	5.6	0.47
Cotton (0.09 lb ai/A/App.; 3 app/yr; 7 day intervals; aerial and ground equipment)					
Short grass	1000	57	0.06	20	0.35
Tall grass	1000	26	0.03	8.5	0.33
Broadleaf forage, small insects	1000	32	0.03	10.7	0.33
Large insects, Seeds	1000	3.55	0.00	1.66	0.47
Potato (0.078 lb ai/A/App.; 3 app/yr; 10 day intervals; ground and aerial equipment)					
Short grass	1000	47	0.05	16.6	0.35
Tall grass	1000	21	0.02	6.9	0.33
Broadleaf forage, small insects	1000	26	0.03	8.7	0.33
Large insects, Seeds	1000	2.92	<0.01	1.36	0.47

APPENDIX F: Data Requirements for Novaluron

Table 1: Environmental Fate Data Requirements for Novaluron			
Guideline #	Data Requirement	Parent Novaluron	Study Classification
161-1	Hydrolysis	44961008	Acceptable
161-2	Photodegradation in Water	45638203	Acceptable
161-3	Photodegradation on Soil	45638204	Acceptable
161-4	Photodegradation in Air	N/A	
162-1	Aerobic Soil Metabolism	44961009 44961010	Acceptable Supplemental
162-2	Anaerobic Soil Metabolism	N/A	
162-3	Anaerobic Aquatic Metabolism	45638205 45638207/45789203	Supplemental Partially Acceptable
162-4	Aerobic Aquatic Metabolism	45638206	supplemental
163-1	Leaching-Adsorption/Desorption	44961011 44961012 45638201 45638202	Acceptable Supplemental Acceptable Acceptable
163-2	Laboratory Volatility	N/A	
163-3	Field Volatility	N/A	
164-1	Terrestrial Field Dissipation	45638403 45638404 and 45789204	Supplemental Aacceptable
164-2	Aquatic Field Dissipation	45785801	Supplemental
164-3	Forestry Dissipation	N/A	
165-4	Accumulation in Fish	45785802 45638405 45638215	Supplemental Supplemental Supplemental
165-5	Accumulation- aquatic non-target	N/A	
166-1	Ground Water- small prospective	N/A	
201-1	Droplet Size Spectrum		
202-1	Drift Field Evaluation		
Non-guideline	Effects on Non-target Microorganisms-	45638217	Supplemental

Table 2: Ecological Effects Data Requirements for Novaluron					
Guideline #		Data Requirement	Formulation	MRID #'s	Study Classification
71-1	850.21	Avian Oral LD_{50}	Parent	454768-01 454990-01	Core Supplemental[a]
71-2	850.22	Avian Dietary LC_{50}	Parent	454990-02 454990-03	Core Core
71-4	850.23	Avian Reproduction	Parent	456382-18 456382-19	Core Core
72-1	850.1075	Freshwater Fish LC_{50}	Parent Rimon 10EC 275352 I (degradate)	454990-04(05) 456383-14 454990-06	Supplemental[b] Supplemental[b] Core
72-2	850.101	Freshwater Invertebrate Acute LC_{50}	Parent Rimon 10 EC 275352 I (degradate)	454768-02 456383-13 454990-07	Invalid[c] Supplemental[d] Supplemental[e]
72-3(a)	850.1075	Estuarine/Marine Fish LC_{50}	Parent	456382-10	Supplemental[f]
72-3(b)	850.1025	Estuarine/Marine Mollusk EC_{50}	Parent	456382-08	Core
72-3©	850.1035 850.1045	Estuarine/Marine Shrimp EC_{50}	Parent Rimon 10EC	456382-09 460862-03	Core Core
72-4(a)	850.14	Freshwater Fish Early Life-Stage	Parent Parent Rimon 10EC	456382-16 456382-13 456384-06	Supplemental[g] Invalid[h] Supplemental[g]
72-4(b)	850.1300 850.1350	Aquatic Invertebrate Life-Cycle	Parent (freshwater) Parent (marine)	456382-11 456382-12	Core Supplemental[i]
72-5	850.15	Freshwater Fish Full Life-Cycle	Parent	457858-05	Invalid[j]
122-1(a)	850.41	Seed Germ./Seedling Emergence			
122-1(b)	850.415	Vegetative Vigor			
122-2	850.44	Aquatic Plant Growth	Parent Rimon 10EC 275382 I (dgradate)	456382-21 456384-11	Supplemental[h] Core Core
123-1(a)	850.4225	Seed Germ./Seedling Emergence (Tier 2)			N/A

Table 2: Ecological Effects Data Requirements for Novaluron					
Guideline #		Data Requirement	Formulation	MRID #'s	Study Classification
123-1(b)	850.425	Vegetative Vigor (Tier 2)			N/A
123-2	850.44	Aquatic Plant Growth (Tier 2)			N/A
141-1	850.302	Honey Bee Acute Contact LD_{50}	Parent Rimon 10EC	456382-20 456382-20	Core Core
141-2	850.303	Honey Bee Residue on Foliage			

[a] Could be up-graded to CORE if additional information is submitted.
[b] Despite several deviations from protocol, the compound was tested above the limits of solubility.
[c] Invalid due to high variability of mean measured concentrations. The test must be repeated. In addition, a sediment toxicity test performed in accordance with EPA sediment toxicity protocols must be conducted.
[d] Measured concentrations not centrifuged. However, this test does not have to be repeated.
[e] Several deviations may have impacted the water quality of this study.
[f] Stability measurements not consistent. The test must be repeated above the limits of solubility.
[g] Not performed to EPA guideline specifications.
[h] Numerous deviations from the protocol. Study should be repeated.
[i] Daily survival and mortality data were not provided. The first day of brood release was not reported, and second generation were not observed daily for at least 4 days for survival, development, and behavior. Since second generation were counted and then discarded, this study is not repairable.
[j] Raw data for survival of both generations and growth of the F_0 generation not provided. Could be up-graded to supplemental if raw data were submitted.
[k] Light intensity too high.